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

REPLY BRIEF FOR PETITIONER

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CORPORATE DISCLOSURE STATEMENT

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

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INTRODUCTION

Respondent's brief in opposition is telling in what it does *not* say. It does not deny that § 112 requires a patent's specification to disclose every element of the claimed invention. It does not deny that a two-tiered approach to written description—one that mandates full disclosure of some elements, but allows "substantially equivalent" disclosure of others—is inconsistent with the statutory text and longstanding precedent. And it does not deny that such a bifurcated written-description test conflicts with the purposes underlying § 112 and risks significant harm to the inventing community and the public at large.

In short, respondent does not dispute that the question presented meets the criteria for certiorari. As Actavis explained in the petition, the decision below replaced a workable test, faithful to the written-description statute, with an amorphous, watered-down inquiry. By loosening the requirement that an inventor disclose *every* element of a claimed invention, the Federal Circuit's new rule allows a patentee to 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). Patentees are already exploiting this new "substantial equivalence" test as a basis to expand their claims beyond their specific disclosures. *See* AAM Br. 10. And by loosening the written-description requirement in such an arbitrary and indeterminate way, the Federal Circuit has harmed both competition *and* certainty.

Respondent's attempt to square the decision below with prior holdings relies on sleight of hand. Respondent emphasizes precedent allowing a patent's

specification to contain "an equivalent description of the claimed subject matter." *E.g.*, *Lockwood* v. *Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). But those decisions contemplate differences in *wording*—a patent's specification need not use "exactly the same terms as used in the claims." *Id.* (citation omitted). By contrast, the decision below allows differences in *substance* between claim and specification. That is why it is wrong.

Respondent falls back to several putative vehicle concerns, but none withstands scrutiny. For example, respondent argues that language specific to the '195 patent itself incorporates "substantial equivalence." But respondent's argument is based on a defined term that *does not appear* in the relevant claim—and the Federal Circuit did not adopt that argument in any event. Respondent also emphasizes the similarity between USP 1 and USP 2. But the question presented is whether, as a legal matter, a substantial equivalent can suffice.

By answering "sometimes," the divided decision below creates the worst possible rule: so broad as to harm competition, and so unclear as to deprive the public of clarity. The Court should grant certiorari and reverse.

ARGUMENT

A. The Federal Circuit's New Rule Conflicts With The Text Of § 112 And Settled Precedent.

A patent must both "distinctly claim[] the … invention" and "contain a written description of the invention"—the *same* invention. 35 U.S.C. § 112. As

the petition explains (at 24-25), the Federal Circuit's new written-description test is inconsistent with that statutory language. Respondent has no rejoinder: it does not spare the statutory text even a passing mention.

Instead, respondent focuses on harmonizing the Federal Circuit's cases—but only by reimagining the cases it cites. And even if respondent could find support in some earlier decisions, that would only confirm that certiorari is necessary to resolve a conflict.

1. Respondent's arguments about precedent rely largely on an apples-to-oranges comparison. According to respondent, a number of decisions have blessed "equivalent" or non-"literal" disclosures—just as (respondent says) the Federal Circuit did here. Opp. 14-17. But the cases on which respondent relies are about differences in *phrasing* between a patent's specification and its claims, not differences in *substance* of the kind the decision below allows for the first time.

Consider *Lockwood*, the lodestar of respondent's analysis. *See* Opp. 15-16. "Although the exact terms need not be used *in haec verba*," *Lockwood* held, "the specification must contain an equivalent description of the claimed subject matter." 107 F.3d at 1572. That is, differences in wording are allowed, but differences in substance are not. If there were any doubt, the very next sentence resolves it: "A description which renders [the invention] obvious … *is not sufficient*." *Id.* (emphasis added). In other words, inventors may take different linguistic routes to describing an invention, but what they describe must

be *the actual invention*—not some variant, not even an "obvious" variant.

Respondent's other citations similarly recognize that the written description need not "correspond[] literally to the claim language," or that the claims need not "be described *in ipsis verbis*" in the specification. Opp. 17. In English or Latin, the point is the same: these authorities are all about *wording*.[1] Cases have long recognized that a patent claiming "a rose" may provide its written description by another name ("*Rosa rubiginosa*," "symbol of the House of York," etc.). But the law has never deemed the disclosure of another flower altogether—even if "equivalent"—sufficient to satisfy § 112.[2]

For this reason, the decision below represents a substantial departure from settled precedent. The '195 patent's specification did not use varying language to disclose the critical claim element—a dissolution profile measured using USP 2. It disclosed something else entirely: a dissolution profile measured using a distinct testing method that yields different results. Pet. 11-13. Respondent's repeated

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[1] In quoting Patent Office guidance, respondent tries to obscure that point with a carefully placed ellipsis. *See* Opp. 17. The omitted text reveals the focus on language: "The subject matter of the claim need not be described literally (*i.e.*, *using the same terms or* in haec verba) in order for the disclosure to satisfy the description requirement." Manual of Patent Examining Procedure § 2163.02 (emphasis added).

[2] Respondent attempts (at 26-27) to explain away the written-description cases cited in the petition, but offers only *factual* distinctions.

invocation of "the *in haec verba* standard," Opp. 16, is thus beside the point.

Even the decision below *itself* refutes respondent's characterization of prior precedent. It acknowledged that "as a general matter"—*i.e.*, putting aside its newly created exception for non-"operative" claim steps—"written description may *not* be satisfied by so-called equivalent disclosure." Pet. App. 13a-14a (emphasis added). In other words, the Federal Circuit, unlike respondent, candidly acknowledged that its decision breaks from precedent.

2. Respondent also contends (at 18-21) that the written-description requirement "requires flexibility and rejects rigidity." But respondent turns to decisions from this Court discussing different, *non-statutory* doctrines—and does not attempt to square its appeal to "flexibility" with the statutory text.

As for the lower-court written-description cases respondent cites, they are about how general or specific a patent's written description must be. *Ariad*, 598 F.3d at 1351 ("[T]he *level of detail* required to satisfy the written description requirement varies depending on the nature and scope of the claims …." (emphasis added)); *Vas-Cath Inc.* v. *Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991) (explaining that the appropriate level of detail may vary on a "case-by-case" basis (citation omitted)). But here, the '195 patent did not skimp on *detail*; it failed to disclose the USP 2 limitation at all.[3] And the Federal Circuit

[3] Respondent notes (at 11) that the USP 2 test is "mentioned" in the '195 patent's specification. But that mention comes in a "Definitions" section that is not pertinent to the claim at issue

okayed such omissions, whenever the element is not "operative" (whatever that means) and a "substantially equivalent" element appears somewhere in the specification. That holding added "a new rule to th[e] court's long-standing written description jurisprudence." Pet. App. 25a (Prost, C.J., dissenting).

3. Seeking to bridge the gap, respondent cites several cases that, in its view, hold that a patent's specification need not disclose certain claim limitations at all. *See* Opp. 16, 23-25. Respondent misunderstands or mischaracterizes these decisions.[4] But

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here. *See* Pet. 12-13; pp. 8-9, *infra*. And there is no dispute that the *relevant data* in the specification do not report results generated using USP 2. *See* Pet. 12.

[4] For example, respondent says (at 23-25) that *Ives* v. *Hamilton*, 92 U.S. 426 (1876), relieved the patentee of an obligation to describe a particular claim limitation (the angle of a saw's curved guides) because the limitation was not the "essence of the improvement." But *Ives* did not excuse the patentee from describing a claim limitation—it held that the angle *was not a limitation*. That is, the patent-in-suit did not claim any particular angle: everything from a "slight angle" to "perpendicular" was within the scope of the claim. *Id.* at 431. Here, by contrast, all parties agree that the USP 2 clause limits claim 11. *See* Pet. 18 n.5.

In other cases, the court found the limitation was adequately described in the specification—far from sanctioning the "absence of ***any*** corresponding disclosure," Opp. 16. *E.g.*, *All Dental Prodx, LLC* v. *Advantage Dental Prods., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002) (specification made clear that the invention involved heating a mass with no identifiable form or shape, just as the patent later claimed); *Union Oil Co. of Cal.* v. *Atl. Richfield Co.*, 208 F.3d 989, 999 (Fed. Cir. 2000) (jury verdict survived JMOL based on trial testimony that the specification disclosed the claimed ranges).

even if respondent were reading them correctly, respondent has simply identified *yet another* split in the Federal Circuit's case law. As explained in the petition, the Federal Circuit has consistently recognized that § 112 requires a written description of "the invention, with *all* its claimed limitations." *Regents of the Univ. of Cal.* v. *Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (emphasis added) (citation omitted). That is required not only by the statute, but by this Court's decisions treating every claim limitation as material. Pet. 25-26. If respondent is right that there exists a body of contrary authority, that only underscores the need for this Court's review.

B. The Federal Circuit's New Rule Risks Significant Harm Both To The Inventing Community And The General Public.

The Federal Circuit's disruption of longstanding precedent warrants this Court's attention. As the petition explains (at 6-8, 27), the written-description requirement serves two vital purposes: it ensures that a patentee does not claim more than what he or she actually invented, and it informs the public of what that invention is. The Federal Circuit's new test undermines both aims. For one thing, the rule is amorphous, engendering uncertainty in an area where predictability is key. *See* Pet. 28-29; AAM Br. 11-15. Moreover, the new rule opens the door to abuse, by allowing applicants to smuggle previously undisclosed claims into a patent application while maintaining the benefit of the original filing date. *See* Pet. 29; AAM Br. 9-11. Here, the smuggled-in limitation was the only reason the relevant claim was not rejected as obvious during prosecution. Pet.

3, 13-14, 30. And as AAM explains (at 10), patentees are already trying to leverage the decision below to get and defend additional patents, capturing products that designed around their original patents.

Respondent shrugs. It does not dispute that patentees are already trying to exploit the hole the Federal Circuit has torn in the written-description statute, or that the issue will recur frequently. *See* Opp. 31-33. Instead, the only argument respondent can muster is that some of the pernicious effects that the decision below will create—*e.g.*, the potential for abuse of "continuation" applications—were not yet felt *in this case*. Opp. 32.[5] But that does not diminish the importance of the question presented; it *heightens* the importance of closing the loophole promptly.

C. This Case Presents An Ideal Vehicle To Address A Purely Legal Question.

Beyond its arguments about precedent, respondent suggests that this case would make a poor vehicle. But its objections are unfounded.

1. The Federal Circuit's Holding Does Not Turn On The Wording Of Respondent's Patent.

Respondent argues that it can prevail based on the language of the '195 patent itself. Specifically, respondent argues (at 6) that the '195 patent "expressly permits dissolution tests 'substantially

[5] Indeed, respondent makes the remarkable assertion (at 32) that Actavis lacks Article III standing to point out the recurring significance of the decision below.

equivalent' to USP 2." That is not what the patent says *or* what the Federal Circuit relied on.

a. Respondent points (at 6) to a single passage of the specification's "Definitions" section, defining the term "release rate": "An 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. This language, respondent suggests, allows *any* testing method that is "substantially equivalent" to USP 2 to provide the necessary written-description support for claim 11—the only claim of the '195 patent at issue in this case.

The problem is that the defined term on which respondent's argument hinges, "release rate," does not appear in claim 11. That claim speaks only of a dissolution profile measured using USP 2. Pet. App. 99a-100a. Meanwhile, the term "release rate" *does* appear in four other claims—6, 8, 9, and 10—none of which respondent asserted against Actavis's product. Pet. App. 99a.[6] Even if references to "release rate" allow for variance in "test conditions," reference to USP 2 means USP 2.

b. The language respondent cites played absolutely no role in the Federal Circuit's decision. Even though respondent pressed this point, Resp. C.A. Br. 19-20, the Federal Circuit did not base its decision on

[6] In fact, claim 11 originally used the term "standard dissolution test," but the applicants replaced that term with the specific reference to USP 2 to overcome an obviousness rejection. Pet. 13-14; Pet. C.A. Br. 24-25, 35-37.

this or any other language in *this* patent's specification. Instead, it announced a broad legal rule: "While as a general matter written description may not be satisfied by so-called equivalent disclosure," such "so-called equivalence" is enough where it "relates only to … [non-]operative claim steps." Pet. App. 13a-14a. To be sure, the court explained that its *application* of that rule was, "in this case, buttressed by the district court's fact-finding." *Id.* But that does not cabin the breadth of the court's holding—or justify its departure from text and precedent.

2. The Question Presented Does Not Turn On Factual Disputes.

Respondent also strives to recharacterize the petition as disputing the facts, rather than the Federal Circuit's legal error. *See* Opp. 9-14. That is incorrect.

The district court found that, notwithstanding any differences between USP 1 and USP 2, the two tests were at least "substantially equivalent" to one another. Pet. App. 44a-45a. Actavis takes that finding as a given. The question now is its legal effect: even assuming USP 1 and USP 2 are substantially equivalent, is that enough to satisfy § 112? Is disclosing the one legally sufficient to provide a written description of the other? The Federal Circuit said yes. The question presented is whether that is wrong as a legal matter. *See* Pet. i, 31 n.8.

Deciding that legal question does not require relitigating any facts. Using undisputed facts, the petition shows that USP 1 and USP 2 employ different methods and lead to different results. Indeed, the patent's inventor—respondent's witness—testified

that the two tests are not comparable and lead to different results for naltrexone. Pet. 12; *see* Opp. 10. Thus, even if "substantially equivalent," the two methods are, at best, obvious variants of one another. And so the Federal Circuit's new "substantial equivalence" test conflicts with the longstanding rejection of obvious-variant disclosures as sufficient to satisfy § 112. *See* pp. 3-5, *supra*. In short, the parties are operating from an agreed-upon set of facts; they differ only in their understanding of whether § 112 is satisfied.

3. Respondent's Waiver Arguments Are Unfounded.

The requirement of a dissolution profile as specifically measured using USP 2 was critical to the issuance of claim 11; it was inserted to avoid a rejection on the ground that the claimed formulation was obvious over the prior art. *See* Pet. 3, 13-14. Respondent argues (at 27-31) that this aspect of the patent's history is somehow "waived" because Actavis did not argue obviousness or "prosecution history disclaimer" below. But respondent attacks a straw man.

First, the argument is not that the claim *is* obvious; the argument is that adding the USP 2 limitation (in place of a more general "standard dissolution test") *saved the claim* from an obviousness rejection during prosecution. The Federal Circuit suggested that the failure to disclose this claim limitation was excusable, and disclosure of a substantial equivalent was acceptable, because it is non-"operative" and therefore not really important. Pet. App. 13a-14a. Respondent basically agrees. Opp. 25. That contradicts not only this Court's holdings that all limita-

tions are material, Pet. 25-26, but also the history of this patent, because without this limitation, the Patent Office never would have issued this claim. That is why § 112 required a written description of the entire invention, including this limitation.

Second, the question presented has nothing to do with prosecution disclaimer. That doctrine is used to understand a claim's meaning: if the patentee surrendered a specific meaning during prosecution, it cannot later argue that the claim should be construed to reach that specific meaning. *E.g.*, *Omega Eng'g, Inc.* v. *Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). Here there is no dispute about claim 11's meaning; the dispute concerns whether a claim with that scope is *invalid*, because it was not disclosed in the written description. That is exactly what the court below decided—wrongly.

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The Federal Circuit's new rule allows applicants to patent inventions that they did not possess and did not disclose at the time they filed their application. It is now unclear which limitations require real written description and which require only "substantially equivalent" description. What *is* clear is that this new rule weakens the written-description requirement, resurrects otherwise-invalid claims, and harms competition.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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