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 IN OPPOSITION

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QUESTION PRESENTED

Whether the Court should disturb factual findings that a claim limitation reciting a dissolution profile met the written description requirement based on evidence from the patent specification and expert testimony showing that the claimed dissolution profile could be determined by USP 2 or a "substantially equivalent" method such as USP 1, where – contrary to petitioner's claim that the circuit court applied a so-called "substantial equivalence" standard – it in fact applied well-settled written description precedent?

CORPORATE DISCLOSURE STATEMENT

Nalpropion Pharmaceuticals LLC's parent corporations are Currax Pharmaceuticals LLC, Currax Holdings USA LLC, and Currax Holdings LLC.

No publicly held companies own 10% or more of Nalpropion Pharmaceuticals LLC's stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

I. INTRODUCTION

The Court should deny Actavis's petition for a writ of certiorari. The Federal Circuit correctly determined that the District Court did not clearly err in its factual finding that, based on the patent-in-suit and Nalpropion's expert testimony, one skilled in the art would understand the inventors had possession of their invention regardless of whether they used USP 2 or a "substantially equivalent" method such as USP 1 to obtain the claimed dissolution profile. Actavis mischaracterizes that ruling to make it seem like the Court's reference to "substantially equivalent" subject matter created a new legal standard. It did not.

First, the claim at-issue recites a dissolution profile. The '195 patent specification expressly states that this dissolution profile can be determined by USP 2 and methods "substantially equivalent" to USP 2. Expert testimony confirmed that USP 1 was a "substantially equivalent" method to USP 2 and that the '195 specification includes data supporting the dissolution profile in the asserted claim. Thus, it is unsurprising that the District Court looked to the "substantially equivalent" language of the patent. After considering that language and expert testimony, the District Court found there was written support for the claim. The Federal Circuit, applying well-settled precedent, concluded that the District Court did not clearly err in rejecting Actavis's arguments, and in finding USP 1 and USP 2 were substantially equivalent. Contrary to Actavis's petition, the Federal Circuit did not implement a new standard by discussing "substantially equivalent" dissolution

tests—it merely used the standard recited in the patent-in-suit.

Second, Actavis rehashes factual arguments, alleging that "unrebutted" evidence established that USP 1 and 2 were not substantially equivalent. But Actavis ignores that the District Court discredited Actavis's evidence (*e.g.*, pointing out that Actavis's expert contradicted himself), and credited the '195 patent's disclosure and Nalpropion's expert. Actavis further notes that claims to an "obvious variant" of the specification may lack written description support. But neither the Federal Circuit nor the District Court held that the claim recites an obvious variant.

Third, Actavis mischaracterizes precedent on written description. It argues that disclosure "equivalent" to a claim term cannot provide support for that term under § 112. Actavis's own cases state the opposite. *See, e.g., Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) ("[T]he specification must contain an ***equivalent*** description of the claimed subject matter.") (emphasis added). And contrary to Actavis's argument, courts apply a "flexible" written description test that varies based on the knowledge in the art and nature of the invention.

Fourth, Actavis mistakenly argues that the Federal Circuit erred by labeling the dissolution limitation "non-operative." The Circuit Court properly indicated that the "specific, positive steps" of treating obesity constitute "operative" claim limitations in the method. By contrast, the "non-operative" dissolution limitation relates to *in vitro* tests of the formulation used in the method, not a

treatment step. Although the Federal Circuit acknowledged this distinction, it never "disregarded" any limitation. Rather, it accounted for the dissolution limitation's relationship to the invention, as dictated by precedent.

Fifth, Actavis's petition focuses on the prosecution history and prior art. However, Actavis failed to raise those claim construction and obviousness arguments before the District Court.

Lastly, Actavis raises policy concerns. It suggests, *inter alia*, reconsidering the duration of patent protection, and it disparages the practice of filing continuation applications. But none of these issues are properly before the Court.

II. STATEMENT OF THE CASE

Claim 11 of the '195 patent recites a "method of treating overweight or obesity." *Orexigen Ther., Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 798-99 (D. Del. 2017). It requires administering specific doses of sustained release formulations of two active ingredients (naltrexone and bupropion). *Id.* Actavis does not dispute that the specification provides written description support for those elements. The claim further recites a dissolution profile for naltrexone, which Actavis alleges lacks written description.

The District Court rejected Actavis's written description challenge. It found that the specification sets forth data "falling squarely within the claimed [dissolution] ranges" (*i.e.*, between 39% and 70% released in one hour; between 62% and 90% released in two hours; and at least 99% released in 8 hours.) *Id.* at 801-02. Actavis did not contest that the

specification discloses values within the claimed ranges, and it only took issue with the alleged use of USP 1 rather than USP 2 to obtain certain values. The District Court found any differences between the methods inconsequential in view of: (1) a statement in the '195 patent that all of the dissolution data had been obtained using USP 2 or "test conditions substantially equivalent thereto," and (2) Nalpropion's expert testimony that a person skilled in the art ("POSA") would have understood the inventors possessed their invention regardless of whether they used USP 1 or USP 2. *Id.* It further found the testimony of Actavis's expert, that the two methods substantially differed, lacked credibility because he had equated the two types of dissolution analyses—when it suited his purposes. *Id.* The District Court therefore concluded that Actavis failed to carry its burden to prove by clear and convincing evidence that the claim lacks written description support. *Id.* at 803.

Actavis appealed the written description holding, which the Federal Circuit affirmed in a 2-1 decision. The Federal Circuit deferred to the District Court's fact findings and credibility assessments, including its decision to credit the testimony of Nalpropion's expert over the "untrustworthy, self-serving testimony by Actavis's expert." *Nalpropion Pharms., Inc. v. Actavis Labs. FL, Inc.,* 934 F.3d 1344, 1350 (Fed. Cir. 2019). The Federal Circuit recognized, based on its precedent, that "[i]t is not necessary that the exact terms of a claim be used *in haec verba* in the specification, and equivalent language may be sufficient" under § 112. *Id.* It adhered to that "flexible, sensible" standard in holding that,

"buttressed by the district court's fact-finding, and where the so-called equivalence relates only to resultant dissolution parameters rather than operative claim steps," the District Court did not clearly err in "its fact findings that Actavis had not proven by clear and convincing evidence that claim 11 of the '195 patent is invalid for lack of adequate written description." *Id.* at 1350-51.

Actavis then petitioned for panel rehearing and rehearing *en banc* at the Federal Circuit, based on the Federal Circuit's alleged adoption of a new rule allowing substantially equivalent disclosure to support non-operative claim limitations. Nalpropion opposed Actavis's petition, highlighting: (1) the '195 patent's statement concerning "substantially equivalent" dissolution tests; and (2) the Federal Circuit's acknowledgment in *Lockwood* that an "equivalent" description of the claimed subject matter can satisfy § 112. Actavis's petition had failed to mention either point.

The Federal Circuit denied Actavis's petition without issuing an opinion. No Judge dissented from the denial of rehearing, not even the Chief Judge Prost, who authored the dissent to the panel opinion from which Actavis's arguments here are derived.

III. ARGUMENT

A. The Federal Circuit did not create a new written description rule.

1. The '195 patent expressly permits dissolution tests "substantially equivalent" to USP 2.

Actavis argues that the Federal Circuit created a new "substantially equivalent" rule. It did not. The "substantially equivalent" language came from the patent-in-suit, which states:

> An in vitro release rate is determined by a "standard dissolution test," conducted according to [the USP 2 method] . . . ***or other test conditions substantially equivalent thereto***.

Pet. App. 87a (emphasis added).

At trial, Nalpropion's expert testified that the specification shows the inventors had possession of their invention notwithstanding their use of USP 1 because: (a) the inventors made clear that a "substantially equivalent" method could be used, and (b) a POSA would view the USP 1 and USP 2 methods as substantially equivalent. *See, e.g.,* Appx011416-011417.

Crediting Nalpropion's expert (Dr. Treacy), the District Court found adequate written description support:

> I agree with Plaintiff that the specification would indicate . . . that all of the dissolution data reported in the patent was obtained "using Apparatus 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***." ('195 patent at 6:52-55).
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> * * *
>
> Dr. Treacy further testified that a person of ordinary skill "would find reasonable support for the claim limitations in the written description," specifically the upper and lower limits for each of the ranges. (Tr. 660: 12-20). Dr. Treacy also opined that, in the context of the patent, 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. (Tr. 663:3-9).
>
> * * *
>
> Defendant's emphasis on the purported differences between the two methods of measuring dissolution profiles [USP 1 and USP 2] seems to be misplaced as even its own expert was willing to favorably compare the two methods when it was to Defendant's benefit to do so.
>
> * * *
>
> I hold that Defendant has not proven by clear and convincing evidence that claim 11 of the '195 patent is invalid for lack of written description.

282 F. Supp. 3d at 801-02 (emphasis added).

In analyzing written description, the District Court made plain that it adhered to Federal Circuit's *en banc* guidance. *Id.* at 800 ("[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."), quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

The Federal Circuit highlighted that "both parties point[ed] to evidence regarding whether a person of ordinary skill would understand USP 1 and USP 2 to be 'substantially equivalent.'" *Nalpropion*, 934 F.3d at 1350. The Federal Circuit deferred to the District Court's fact findings and credibility assessments, finding no clear error:

> The district court performed precisely its fact-finding function, weighing credibility of testimony. . . . [T]he court credited Nalpropion's expert, Dr. Treacy, as more credible over what it interpreted as untrustworthy, self-serving statements by Actavis's expert, Dr. Mayersohn. . . . We do not disturb this finding . . . .
>
> [T]he district court concluded, on the facts, that USP 1 and USP 2 would be "substantially equivalent[.]" Thus, it found that, irrespective of the method of measurement used, the specification shows that the inventors possessed the invention . . . and adequately described it. We conclude that this finding does not present clear error.

Id. at 1350-51.

The Federal Circuit thus concluded, based on the patent specification and fact-finding "***in this case***," that the District Court did not clearly err. *Id.* at 1351 (emphasis added). So neither the District Court nor Federal Circuit established any new rule or set any noteworthy precedent on written description.

2. Actavis mischaracterizes the record and the decisions below.

a. Actavis's factual arguments are irrelevant and incorrect.

Actavis attempts to frame its arguments as "purely legal" by contending that it does not challenge "whether USP 1 and USP 2 are *in fact* 'substantially equivalent.'" Pet. at 31 & n.8 (emphasis original). Notwithstanding that statement, Actavis spends considerable space rehashing factual arguments that it advanced below regarding alleged differences between USP 1 and USP 2. Between the District Court and Federal Circuit, such factual arguments were already considered three times and rejected. They should be rejected here as well. *See* S. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings . . . ."). Regardless, Actavis's factual arguments are wrong.

Actavis contends "unrebutted" evidence established that USP 1 and USP 2 would have produced different results. Pet. at 23. But the District Court discredited Actavis's only evidence of differences, finding that "Dr. Mayersohn's theoretical opinion that the methods would yield different results is at odds with his reliance on a prior art reference using the basket method to argue that claim 11, which

specifies the paddle method, was obvious." 282 F. Supp. 3d at 802 ("[Actavis's] own expert was willing to favorably compare the two methods when it was to [Actavis's] benefit to do so."). That alone supports the District Court's holding because Actavis failed to carry its burden. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1573-74 (Fed. Cir. 1985) ("[T]he district court correctly placed the burden of overcoming the presumption of validity by demonstrating insufficiency of disclosure on [defendant], and found that [defendant] had not shown by clear and convincing evidence that it had met that burden."). While Actavis invokes the inventor's testimony that "one would not necessarily expect to get the ***same*** release profile" with different dissolution tests (Appx011319-20 (emphasis added); *see* Pet. at 12), the District Court considered that testimony and concluded that it did not "matter[] whether the two methods would yield ***exactly the same*** results." *Orexigen*, 282 F. Supp. 3d at 802 (emphasis added); *see Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 1566 (Fed. Cir. 1991) (a patent "does not have to describe exactly the subject matter claimed"); *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1533 (Fed. Cir. 1992) (same). And Actavis fails to mention evidence that the District Court credited in finding USP 1 and 2 substantially equivalent, such as Nalpropion's expert testimony on a POSA's understanding of the '195 patent's disclosure. *Orexigen*, 282 F. Supp. 3d at 801-02; *see* Appx011410 (656:14-22), Appx011411-011412 (657:23-658:9), Appx011416-011417 (662:20-663:4).

Actavis also raises new factual arguments. Actavis tries to salvage its expert's discredited opinion with

evidence outside the record, such as a Youtube video on USP 1 and 2. Pet. at 11 n.4. That video published after the priority date of the '195 patent and thus would not support Dr. Mayersohn's opinion even if it were properly before the Court. *Ariad*, 598 F.3d at 1355-57 (finding "evidence of what one of ordinary skill in the art knew in 1990 or 1991 . . . irrelevant to the question whether the inventors were in possession of the claimed invention as of the 1989 priority date").

In addition, Actavis now alleges for the first time that the USP 2 "test is mentioned nowhere in the patent's specification." Pet. at 3, 30 ("[T]he only identifiable test in the specification is USP 1."). But the specification explicitly identifies USP 2 when discussing dissolution testing "conducted according to United States Pharmacopeia 24th edition (2000) (USP 24), pp. 1941-1943, ***using Apparatus 2*** described therein at a spindle rotation speed of 100 rpm and a dissolution medium of water, at 37° C." Pet. App. 87a (emphasis added).

In fact, the specification includes data resulting from the USP 2 test, *e.g.*, data at column 13, lines 35-45 was obtained from USP 2. Appx000186.[1] Dr. Treacy testified that a POSA would likewise understand that Example 3, which also does not mention USP 1, used the "standard dissolution test the inventors had defined earlier in the specification," *i.e.*, USP 2. Appx011415-011416.

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[1] Column 13 states that the "[i]n vitro release rate is determined by a standard dissolution test as described above." *Id.* The description above expressly refers to USP 2. Pet. App. 87a.

Actavis also asserts without explanation that the disclosure "discuss[es] dissolution tests that differ from USP 2 as set forth in claim 11." Pet. at 12. That makes no sense. Actavis admits "Apparatus 2" refers to the "USP 2 Paddle Method" in claim 11. *Id.* at 11. And claim 11 recites the same conditions disclosed in the specification (100 rpm and a dissolution medium of water, at 37° C). Pet. App. 87a. Actavis also dismisses the specification's discussion of USP 2 because it forms part of the definition of a term, "release rate," that does not appear in the claim 11. *Id.* at 13. Actavis cites no authority for ignoring disclosure in the specification when analyzing written description. The definition of "release rate" refers to USP 2 dissolution test that appears in claim 11 and thus undisputedly supports the USP 2 dissolution limitation.

b. Neither the District Court nor the Federal Circuit held that an obvious variant provides written description support.

Actavis finds it difficult to "square" the Federal Circuit's analysis in this case with the Court's "prior invalidation of claims directed to 'obvious variants' of the disclosed invention." Pet. at 23, quoting *Lockwood*, 107 F.3d at 1572. But as shown above, the District Court's decision and Federal Circuit's affirmance were based on the particular facts of the case where the specification itself specifically stated USP 2 or "test conditions substantially equivalent thereto," and thus analyzing substantially equivalent methods was necessary, and thus was not and could not be inconsistent with precedent. Moreover, Nalpropion argued and showed that Alvogen failed to

meet its burden of proof because its expert made contradictory ***factual*** statements when testifying about obviousness and written description, which undermined his credibility. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) (obviousness under § 103 includes underlying factual questions, such as the differences between the prior art and the claims); *Vas-Cath*, 935 F.2d at 1563 ("[T]he 'written description' requirement of § 112 is a question of fact[.]"). Those direct, factual contradictions were material, and apply without regard to legal context, as the District Court recognized. 282 F. Supp. 3d at 801-02; *see, e.g., Allergan, Inc. v. Sandoz, Inc.*, 796 F.3d 1293, 1309 (Fed. Cir. 2015) (finding adequate written description for "clinical profile limitations [that] the specifications d[id] not explicitly describe" in view of an argument that defendants made in their "obviousness challenge"); *Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000) (infringement allegation rendered patent invalid); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (reversing in view of "internally inconsistent" fact findings under § 103 and § 112).

Specifically, the District Court found that Dr. Mayersohn's allegation that prior art USP 1 data fell within the range in claim 11 of the '195 patent conflicted with his "theoretical" opinion (unsupported by any data) that USP 1 and USP 2 "would yield different results." *Orexigen*, 282 F. Supp. 3d at 801-02. The Federal Circuit mentioned obviousness in its § 112 analysis merely to explain the deference it was giving to the District Court's finding that Dr. Mayersohn lacked credibility because of his

inconsistent testimony when discussing written description and obviousness. *Nalpropion*, 934 F.3d at 1350.

Moreover, the "obvious variant" language came from *Lockwood*, where the Federal Circuit found it "not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to ***speculate*** as to modifications that the inventor might have envisioned." 107 F.3d at 1572 (emphasis added). But the '195 patent requires no speculation as to what the inventors envisioned—it expressly states that they used USP 2 or a substantially equivalent method, and discloses data showing that both USP 1 and USP 2 could be used to determine the dissolution profile of their invention.[2]

B. Actavis's attempts to manufacture a split in the case law fail.

The Federal Circuit accurately set forth and properly applied the law on written description, as confirmed by its unanimous decision to deny Actavis's petition for panel rehearing and rehearing *en banc*.

1. The Federal Circuit accurately stated the law on written description.

Actavis asserts that the Federal Circuit misstated the law by: (1) recognizing that an equivalent

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[2] Actavis contravenes its own authority by conflating an "obvious variant" with an "equivalent." The Court in *Lockwood* contrasted obvious variants and equivalents, making clear that claims reciting an "equivalent" of the disclosure in the specification do ***not*** lack written description support. 107 F.3d at 1572; *see* Section III(B)(1)(a), *infra*.

description of claimed subject matter can suffice under § 112; and (2) adhering to a "flexible" test instead of a "rigid[]" one. Actavis's own authority undermines both arguments.

a. Actavis's own authority requires only an "equivalent" description.

According to Actavis, the Federal Circuit departed from precedent by allowing an "equivalent" disclosure to support claims. Pet. at 3-4. Actavis's primary authority disproves that notion. It cites *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) more than a half dozen times, arguing "*Lockwood* make[s] clear that '[a] substantially equivalent disclosure . . . cannot satisfy the written description requirement.'" Pet. at 18. Actavis, however, quotes nothing from *Lockwood* concerning substantial equivalence. Instead, it relies on the Judge Prost's dissent from panel decision, without acknowledging that neither Judge Prost nor any other Judge dissented from the decision to deny Actavis's petition for rehearing.

Lockwood itself rules out Actavis's interpretation. The Court there explained that, "[a]lthough the exact terms need not be used *in haec verba*, . . . the specification must contain an ***equivalent*** description of the claimed subject matter." *Lockwood*, 107 F.3d at 1572 (emphasis added). Actavis continues to ignore that language even though it matches almost verbatim the Federal Circuit's articulation of the law in this case. *See Nalpropion*, 934 F.3d at 1350 ("It is not necessary that the exact terms of a claim be used *in haec verba* in the specification, and equivalent language may be sufficient.").

Actavis cites no authority contradicting *Lockwood*. It relies on *Ariad*, but there the full Federal Circuit endorsed *Lockwood*'s standard. 598 F.3d at 1352 ("[T]he description requirement does not demand . . . that the specification recite the claimed invention *in haec verba*[.]"), citing *Lockwood*, 107 F.3d at 1572.

Actavis downplays *Ariad*'s directive as relating to "language alone," *i.e.*, differences in "*wording*" between the specification and claims. Pet. at 23 (emphasis original). But that unsupported argument contradicts Federal Circuit decisions applying the *in haec verba* standard to uphold the validity of claims despite the absence of ***any*** corresponding disclosure in the specification. *See, e.g., Pozen Inc. v. Par Pharmaceutical, Inc.*, 696 F.3d 1151, 1166-67 (Fed. Cir. 2012) (rejecting argument that "finished pharmaceutical container" lacked written description support, even though specification did not describe any container); *All Dental Prodx, LLC v. Advantage Dental Products, Inc.*, 309 F.3d 774, 777-79 (Fed. Cir. 2002) (rejecting argument that "a mass that does not have a specific preformed size and shape" lacked written description support, even though "no mention of the starting material's shape or form [appeared] in the patent specification"); *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997-98 (Fed. Cir. 2000) (rejecting argument that gasoline compositions lacked written description support, even though specification did not describe the compositions themselves, only their properties).

Moreover, contrary to Actavis's theory, Courts have found written description adequate where the specification disclosed "something similar to—but substantively different from—" the claim language.

Pet. at 28; *see Ralston Purina Co. v. Far-Mar-Co, Inc.*, 586 F. Supp. 1176, 1204-05 (D. Kan. 1984), *aff'd in relevant part and rev'd in part on other grounds*, 772 F.2d 1570, 1577 (Fed. Cir. 1985) (finding "two examples disclos[ing] the addition of roughly 25% and 27% moisture" supported a claim reciting "an added moisture content of at least 25%"); *see generally Vas-Cath*, 935 F.2d at 1563 ("[R]anges found in . . . claims need not correspond *exactly* to those disclosed in" the specification) (emphasis original) (citation omitted).

Actavis also relies on the Patent Office's guidance but, as it did with *Lockwood*, leaves out the most pertinent part: "[t]he subject matter of the claim ***need not be described literally*** . . . in order for the disclosure to satisfy the description requirement." Manual of Patent Examining Procedure § 2163.02 (emphasis added). That statement accords with *Lockwood* as well as decisions from the Federal Circuit's predecessor. *See In re Wertheim*, 541 F.2d 257, 262, 265 (C.C.P.A. 1976) ("If lack of literal support alone were enough to support a rejection under § 112, then the statement . . . that 'the invention claimed does not have to be described *in ipsis verbis* in order to satisfy the description requirement of § 112,' is empty verbiage.") (citation omitted); *In re Schneider*, 481 F.2d 1350, 1356 (C.C.P.A. 1973) (rejecting as "too strict" a standard requiring "written description corresponding literally to the claim language involved"); *see also Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) (cited by Actavis) (written description test does not hinge on "the presence or absence of literal support in the specification for the claim language") (citation omitted).

Nor does Actavis identify any decision by this Court that undermines the equivalence guidelines in *Lockwood*. It cites only one Supreme Court case, *Gill v. Wells*, 89 U.S. 1 (1874), that even mentions equivalents in the context of written description. *Gill* lends no support to Actavis's argument. There, patentee attempted to add new inventions in a reissue application "***without any allegation that they are the equivalents*** of the one whose description is stricken out." *Id.* at 28. The Court held that patentees cannot obtain reissue claims to another invention where "there is no suggestion, indication, or intimation [in the original specification] that any other invention of any kind has been made." *Id.* at 24. Here, the original specification contains more than a mere "intimation" concerning equivalent dissolution tests. It explains that the inventors obtained dissolution data using USP 2 or a "substantially equivalent" method, and it discloses USP 1 data in addition to USP 2 data.

Actavis also relies on *Hubbell*, *Warner-Jenkinson*, and *Festo*, which recognized that claims ***can*** cover equivalents in the context of infringement. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). None of those decisions held that equivalents ***cannot*** provide written description support for claims.

b. Actavis's own authority requires flexibility and rejects rigidity.

Actavis takes issue with the Federal Circuit's statement that "[r]igidity should yield to flexible, sensible interpretation," but does not identify a single case endorsing rigidity over flexibility. Pet. at 4 (citation omitted).

i. Actavis's Federal Circuit case law undermines its position.

Actavis relies on *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991), but there the Federal Circuit ***reversed*** summary judgment of invalidity and "stress[ed] the fact-specificity of" § 112, *i.e.*, flexibility:

> The primary consideration is *factual* and depends on . . . the amount of knowledge imparted to those skilled in the art by the disclosure. Precisely how close the description must come to comply with § 112 must be left to case-by-case development. What is needed . . . will necessarily vary depending on the nature of the invention . . . [E]ach case must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.

Vas-Cath, 935 F.2d at 1562 (emphasis original) (citations and quotation marks omitted); *see also Capon v. Eshhar*, 418 F.3d 1349, 1357, 1360 (Fed. Cir. 2005) (rejecting argument that "§ 112 imposes a *per se* rule": "[s]ince the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science").

Actavis's other Federal Circuit authority also eschewed rigid rules. In *Ariad*, the full Court made clear that "the level of detail required to satisfy the written description requirement ***varies depending*** on the nature and scope of the claims and on the complexity and predictability of the relevant technology." 598 F.3d at 1351. It therefore endorsed flexibility over rigidity. *Id.* ("[W]e do not try here to

predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set out any bright-line rules . . . .").

ii. Actavis's Supreme Court case law undermines its position.

This Court likewise never set forth any rigid written description rule. Actavis relies on *Festo* and *Warner-Jenkinson*, which did not involve written description. In any event, the Court in those cases ***rejected*** "literalism" and ***refused*** to "establish[] a *per se* rule." *Festo*, 535 U.S. at 737-38. It declined to adopt a proposal that "might provide a brighter line," and thereby "promote certainty" because case law consistently applied the doctrines at-issue "in a flexible way, not a rigid one." *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 32 n.6 (1997); *Festo*, 535 U.S. at 730, 737-38 (rejecting argument that this "case-by-case approach has proved unworkable"). The Court followed the flexible approach in the case law to avoid disrupting the settled expectations of the "inventing community." *Festo*, 535 U.S. at 739.

The situation here resembles the circumstances in *Festo* and *Warner-Jenkinson*. For centuries the Court has consistently applied a flexible written description test that varies in each case based upon the nature of the invention and knowledge of a POSA. *See Lawther v. Hamilton*, 124 U.S. 1, 9 (1888) ("[T]he specification of the patent . . . is to be construed in the light of the knowledge which existed in the art at the time of its date"). The invention in *Lawler* involved the omission of one step from a prior art process involving several

steps. The Court accounted for the POSA's knowledge in finding the known steps used in the invention "required no particular explanation." *Id.*; *see also Hogg v. Emerson*, 52 U.S. 587 (1850) (jury's finding that specification was "clear enough to be understood by ordinary mechanics" was "all which the law requires").

2. The Courts below properly applied the law on written description.

The District Court and Federal Circuit properly applied the law.

a. The Federal Circuit correctly considered the nature and scope of the invention by recognizing the distinction between "operative" and "non-operative" steps in the method of treatment.

The District Court performed a fact-specific analysis, relying on the knowledge of those skilled in the art based on the disclosure in the '195 patent and as described by Nalpropion's expert. The Federal Circuit correctly deferred to the District Court's factual findings and credibility assessments, while accounting for the nature of the invention in relation to the dissolution limitation in affirming the District Court decision. All of that was well within this Court's jurisprudence. Nevertheless, Actavis takes aim at the Federal Circuit's characterization of the dissolution limitation as "non-operative." Pet. at 4, 17-19. Actavis misses the mark.

Actavis criticizes the Federal Circuit for purportedly lowering the § 112 standard for a limitation that "relates only to resultant dissolution parameters rather than [an] operative . . . step[]"

(*Nalpropion*, 934 F.3d at 1351) in the claimed method of treating obesity. Pet. at 9-10. Actavis asserts that "one written description test" applies to all limitations, and that this Court has never endorsed a "different written description rule" for "less important" limitations. *Id.* at 19-20, 24-28.

The Federal Circuit did not apply a different written description rule to different types of claim limitations. It acknowledged that one overarching standard applies, *i.e.*, whether a POSA would understand the inventors had possession of the invention. *Nalpropion*, 934 F.3d at 1350. It also recognized, however, that the threshold for sufficient disclosure depends on the nature of the invention and how the limitation at-issue fits within it. *Ariad*, 598 F.3d at 1351.

The Federal Circuit began by analyzing claim 11. It determined that some claim limitations relate to a step in the method of treatment (operative limitation), whereas other limitations relate to dissolution tests of the formulation used in the method (non-operative):

> [Claim 11] begins clearly enough by reciting a method of treating overweight or obesity by carrying out the ***specific, positive steps*** of administering a formulation of specific amounts of sustained-release naltrexone and bupropion in twice a day. The claim then records the dissolution data resulting from that formulation.
>
> But that dissolution profile for naltrexone as measured by USP 2 ***relates only to the measurement*** of resultant in vitro parameters,

> not to the operative steps to treat overweight or obesity.

Nalpropion, 934 F.3d at 1350 (emphasis added). The dissent from the panel's decision concurred with the majority's use of "operative." *Id.* at 1356 (Prost, J., dissenting) ("The majority and I agree . . . that claim 11 includes one operative step, which relates to orally administering, among other things, a specific amount of sustained-release naltrexone formulation.") (emphasis added) (citation omitted).

The Federal Circuit then considered the written description support for the dissolution limitation with this factual distinction in mind. But it did not create a new "bifurcated" operative/non-operative legal framework for written description. Pet. at 20. Rather, it properly applied *Ariad*'s guidance to the facts at hand. 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.").

Nor did the Federal Circuit "renounce[] years of established precedent" (Pet. at 4), as courts have always accounted for a limitation's relationship to the invention when assessing the adequacy of disclosure under § 112. For example, in *Ives v. Hamilton*, 92 U.S. 426, 429-30 (1875), the invention improved sawmills with an arrangement that gave saws "vibratory movement," as opposed to the "straight and uniform motion" of conventional saws. The claim required, among other things, "the combination of the saw with a pair of curved guides at the upper end of the saw." *Id.* The Court found the "description of the patent . . . sufficiently specific" despite the lack of disclosure concerning the position of the guides:

> [I]t is properly taken for granted that the practical mechanic is acquainted with the construction of the machine in which the improvement is made; and nothing appears in the case to show that any peculiar position different from that of sawmills constructed in the ordinary way is necessary to render it effective and useful. The ***essence of the improvement has nothing to do with the precise position of the guides***. It is a combination of mechanical means to produce a rocking motion of the saw; and this combination is just as applicable to guides that have a slight inclination as to guides that are perpendicular.

Id. at 431 (emphasis added).

Similarly, in *In re Herschler*, 591 F.2d 693, 698, 700-01 (C.C.P.A. 1979), the court found that one working example involving a single glucocorticosteroid provided written description support for claims to a method of using dimethyl sulfoxide in combination with "steroids in general." The court explained that "[w]ere th[e] application drawn to novel 'steroidal agents,' a different question would be posed." *Id.* at 701 (emphasis added). The court distinguished the written description requirement for claims to "classes of new compounds *per se* or . . . processes using those new compounds" because the claims at-issue recited "the use of known chemical compounds in a manner auxiliary to the invention," which "must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds." *Id.* at 702 (emphasis added); *see also In re Fuetterer*, 319 F.2d 259, 265 (C.C.P.A. 1963) (distinguishing

cases involving "chemical compounds *per se*" where invention involved a "combination" of substances) (emphasis original).

Here, the Federal Circuit's analysis of the "non-operative" dissolution limitation parallels the analyses in *Ives*, *Herschler*, and *Fuetterer*. The '195 patent claims a new method of treating obesity—not a new dissolution test—and the Federal Circuit correctly accounted for that when finding adequate written description support for the dissolution profile. Both "[t]he majority and [dissent] agree[d] that the essence of the claimed invention is 'a method of treating overweight or obesity.'" Nalpropion, 934 F.3d at 1356 (Prost, J., dissenting) (citation omitted). The "essence of the improvement [therefore] has nothing to do with" any selection of USP 2 over USP 1 to measure dissolution. *Ives*, 92 U.S. at 431. And nothing shows that measuring dissolution by USP 2, as opposed to USP 1, is necessary to "render [the method of treatment] effective and useful." *Id.* To the contrary, the specification expressly permits use of USP 2 or a substantially equivalent method, thus making clear that the choice between USP 1 and USP 2 is inconsequential.

Nor did the Federal Circuit "disregard" the dissolution limitation as "[im]material.[3] Pet. at 25-26. If it had, then analysis of the specification's support for that limitation would have been unnecessary. As multiple cases cited by Actavis make clear, claims can encompass "equivalent" subject matter without

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[3] Actavis's cases concerning disregarding immaterial elements, *e.g.*, *Limelight*, *Water-Meter*, *Sabatino*, and *Exxon*, therefore are inapposite. Pet. at 25-26.

rendering any limitation immaterial. *See Warner-Jenkinson*, 520 U.S. at 32 ("[W]hile a lower limit of 6.0, by its mere inclusion, became a material *element* of the claim, that did not necessarily preclude the application of the doctrine of equivalents as to that element.") (emphasis original), citing *Hubbell v. United States*, 179 U.S. 77, 82 (1900) ("[A]ll [elements] must be regarded as material, though it remains an open question whether an omitted part is supplied by an equivalent device or instrumentality.") (citation and internal quotation marks omitted).

b. Actavis's written description cases are inapposite.

None of the cases cited by Actavis undermine the Federal Circuit's application of the law in this case.

In *Lucent*, the Court found no written description support for claims requiring MDCTs (modified discrete cosine transform) coefficients because, *inter alia*, the inventor "had not heard of MDCTs and had not performed work with MDCTs before the" critical date. *Lucent Techs., Inc. v. Gateway, Inc.*, 543 F.3d 710, 719 (Fed. Cir. 2008). But here, Actavis does not dispute that the specification discloses dissolution data and how to obtain that data. Actavis's reliance on *Ariad* and *Chiron* fails for similar reasons. In *Ariad*, the Federal Circuit found inadequate support for claims to "reducing NF-κB activity" because the patent had "no working or even prophetic examples of methods that reduce NF-κB activity." 598 F.3d at 1357-58. In *Chiron*, the Federal Circuit found the inventors "could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist at the time of the[ir]" application. 363 F.3d

at 1255. Actavis does not dispute that the USP 2 and USP 1 dissolution methods existed before the priority date of the '195 patent, or that the inventors conducted their dissolution tests before that date.

In *ICU Medical, Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1378 (Fed. Cir. 2009), the Federal Circuit found inadequate support for medical "valves that operate with a spike and those that operate without a spike," where the "specification describe[d] only medical valves with spikes." Similarly, in *D Three Enters., LLC v. SunModo Corp.*, 890 F.3d 1042 (Fed. Cir. 2018), the Federal Circuit found the specification "disclose[d] one inventive component," yet the claims recited "entirely different inventive components." *Id.* at 1051. Likewise, in *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931), the purported invention "was neither described in the specification nor claimed." Here, the specification states that the inventors obtained dissolution data using USP 2 or "substantially equivalent" methods, discloses dissolution data generated using USP 1 and USP 2, and expert testimony confirmed that USP 1 and USP 2 are substantially equivalent. *Orexigen*, 282 F. Supp. 3d at 801-02; Appx011415-011416.

C. The Court should disregard the arguments neither raised nor passed on below and reject Actavis's attempt to re-litigate the case.

Actavis attempts to construe claim 11 in view of the prosecution history and alludes to obviousness based on the prior art. The Court should ignore these arguments because Actavis failed to timely raise them below, and neither the District Court nor Federal Circuit addressed them.

1. Actavis waived its meritless arguments about the prosecution history.

Actavis focuses on arguments made during prosecution of the '195 patent (Pet. at 5-6, 17), noting that applicants amended claim 11 to recite USP 2. Pet. at 13-14. Actavis relies on *Hubbell*, *Festo*, and *Warner Jenkinson*, where this Court addressed whether an applicant had narrowed the scope of claims based on arguments or amendments during prosecution. The District Court received briefing and held a hearing to resolve disputes as to claim scope, pursuant to this Court's decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Actavis did not argue during the *Markman* proceedings that the inventors disclaimed non-USP 2 dissolution data, nor did it propose any claim construction that would exclude USP 1 data. Moreover, Actavis never asserted before the District Court that claim 11 lacks written description in view of a prosecution history disclaimer. Actavis therefore waived its § 112 arguments that rely on the prosecution history. *See Power Integrations, Inc. v. Fairchild Semi. Int'l, Inc.*, 904 F.3d 965, 972 n.4 (Fed. Cir. 2018) (defendant waived argument that prosecution history dictated claim scope by not raising it before district court); *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, 790 F.3d 1329, 1341 (Fed. Cir. 2015) (defendant waived argument concerning meaning of claim term by failing to raise it during *Markman* proceedings).

In addition, because Actavis never asserted before the District Court that claim 11 lacks written description based on a prosecution history disclaimer, neither the District Court nor the Federal Circuit

ruled on that issue. This Court is a "court of review, not of first view." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 913 (2014) (citation omitted). Actavis identifies nothing to justify a departure from this Court's usual practice of refusing to consider issues "neither raised nor decided below." *Clingman v. Beaver*, 544 U.S. 581, 598 (2005); *see Byrd v. United States*, 138 S. Ct. 1518, 1527 (2018) (finding it "unwise to consider arguments in the first instance" that the lower courts "did not have occasion to address"); *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1652 n.4 (2017) ("[I]n light of . . . the lack of a reasoned conclusion on this question from the Court of Appeals, we are not inclined to resolve it in the first instance."); *City & Cty. of S.F. v. Sheehan*, 135 S. Ct. 1765, 1773 (2015) ("The Court does not ordinarily decide questions that were not passed on[.]"); *Singleton v. Wulff*, 428 U.S. 106, 120 (1976) ("It is the general rule, of course, that a federal appellate court does not consider an issue not passed upon below.").

Regardless, the prosecution history provides no support to Actavis's arguments. First, courts routinely find written description adequate for limitations added during prosecution notwithstanding the absence of literal support for them in the specification. *See Pozen*, 696 F.3d at 1166-67 (claim element added during prosecution had adequate support despite not appearing in the specification); *All Dental*, 309 F.3d at 779 (same). Actavis identifies no authority to the contrary. If anything, cases cited by Actavis weigh against its argument. It relies, for example, on *Warner-Jenkinson* and *Festo*, where the Court held that limitations added during prosecution may nevertheless encompass equivalent subject

matter. *See Festo*, 535 U.S. at 738. Second, applicants did not disclaim data obtained using the USP 1 method. They expressly identified a table with USP 1 data as written description support for claim 11 when they amended it to recite USP 2. Appx007037. Thus, a POSA "reading the prosecution history ***as a whole***" would understand applicants had not clearly and unmistakably narrowed the scope of claim 11 to exclude dissolution data in that table. *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1121 (Fed. Cir. 2016) (emphasis added).

2. Actavis waived its baseless assertions regarding obviousness.

Actavis's insinuation that prior art renders obvious claim 11 amounts to nothing more than conjecture. Actavis did not raise that argument below. Although it served an expert report on obviousness, it withdrew any obviousness challenge before trial. So neither the District Court nor the Federal Circuit addressed the obviousness of claim 11. The Court therefore should disregard Actavis's belated attempts to disparage the invention with attorney argument about "known" ingredients and prior art that the Patent Office considered before allowing the claims. Pet. at 9, 13-14.

In any event, Actavis's obviousness challenge would fail even if it were properly before the Court. Actavis focuses on the finding that prior art rendered obvious certain claims of the '626 and '111 patents, but it overlooks differences between those claims and claim 11 of the '195 patent. Claim 11 recites a method of treatment, whereas the asserted claim of the '111 patent recites a composition. *Nalpropion*, 934 F.3d at

1347-48. And claim 11 requires specific amounts of naltrexone and bupropion, whereas the asserted claims of the '626 patent do not. *Id.* at 1347. Lastly, the asserted claims of the '111 and '626 patents do not contain any dissolution limitation, which Actavis concedes constitutes an "important" element because it predicts "how the drug will be absorbed by a person's body." Pet. at 10. Actavis does not even try to show that prior art discloses the claimed dissolution profile.

D. Policy considerations do not support Actavis's position.

Actavis complains about the duration of the patent term, the cost of pharmaceuticals, and the addition of new matter in continuation applications. Pet. at. 3, 7-10, 16, 31. But those policy arguments should be "addressed to Congress, not this Court." *Warner-Jenkinson*, 520 U.S. at 28.[4] The Constitution reserves for Congress the authority to promulgate patent laws, pursuant to its power to "promote the Progress of Science and useful Arts." U. S. Const., Art. I, § 8, cl. 8. Actavis concedes that Courts cannot "cut[] loose from the statutory text." Pet. at 28-29. Actavis,

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[4] Actavis's assertions about patent "monopol[ies]" (Pet. at 10) neglect to consider the pro-innovation effects of patent protection. Studies have estimated that the average cost of researching, developing, and obtaining approval for a new drug exceeds $2.5 billion. Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," 47 J. Health Econ. 20-33 (2016). And "[o]nly patent protection can make the innovator's substantial investment in development and clinical testing economically rational." Jay Dratler, Jr., "Alice in Wonderland Meets the U.S. Patent System," 38 Akron L. Rev. 299, 313-14 (2005).

however, does just that by trying to inject irrelevant considerations into § 112. Neither the statute nor any case interpreting it allows the Court to consider, for example, the price of Contrave in a written description analysis. *See* Pet. at 9.

Contrary to Actavis's assertions, this case is particularly ill-suited for the judiciary to step into the domain of the legislature as Actavis's policy concerns fail to present an actual case or controversy. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). The '195 patent did not issue from a continuation application, and the original application contained all of the disclosure at-issue. So Actavis has not suffered ***any*** injury, much less an "imminent" and "concrete" injury, relating to continuation practice. *Id.* at 560 (citation omitted). Nor would a ruling in this case redress the speculative harm from "third-party" patentees adding new matter in continuation applications. *Id.* at 560-61 (citation omitted).

Moreover, while Actavis focuses on the policy aims of § 112 (Pet. at 6-8), this dispute did not involve any failure to disclose new information. The inventors of the '195 patent undisputedly disclosed their formulation and method of using it to treat obesity. They also disclosed dissolution data falling squarely within the claimed ranges, as well as values supporting each endpoint of those ranges. The holding thus turned entirely on the known equivalence of the known USP 1 method and the known USP 2 method. And "a requirement that patentees recite known [information], if one existed, would serve no goal of the written description requirement." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1368, (Fed. Cir. 2006). "It would neither

enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention." *Id.*

Accordingly, overturning the Federal Circuit's decision on policy grounds would serve no useful purpose. To the contrary, re-opening fact findings at this stage would only frustrate Actavis's professed aim of reducing "uncertainty." Pet. at 28. It also would "disrupt the settled expectations of the inventing community" (*Festo*, 535 U.S. at 730), which has relied for centuries on a flexible written description test. *See Lawther*, 124 U.S. at 9; *Ives*, 92 U.S. at 430-31.

IV. CONCLUSION

For the foregoing reasons, the Court should deny Actavis's petition for a writ of certiorari.

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Respectfully submitted,

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