Appeal No. 2018-1221

United States Court of Appeals

for the

Federal Circuit

NALPROPION PHARMACEUTICALS, INC.

Plaintiff-Appellee,

v.

ACTAVIS LABORATORIES FL, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the District of Delaware in Case No. 1:15-cv-00451-RGA
Judge Richard G. Andrews

PLAINTIFF-APPELLEE NALPROPION PHARMACEUTICALS LLC'S RESPONSE TO DEFENDANT-APPELLANT ACTAVIS LABS. FL, INC.'S PETITION FOR REHEARING AND REHEARING EN BANC

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel for Plaintiff-Appellee Nalpropion Pharmaceuticals, Inc. certifies the following:

1. Full name of Party Represented by me:	**2. Name of real party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:**	**3. Parent corporations and publicly held companies that own 10% or more of stock in the party:**
Nalpropion Pharmaceuticals LLC	Nalpropion Pharmaceuticals LLC	Currax Pharmaceuticals LLC, Currax Holdings USA LLC, and Currax Holdings LLC

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

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Morris, Nichols, Arsht & Tunnel LLP
Mary B. Graham, Rodger D. Smith II, Stephen J. Kraftschik

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47. 4(a)(5) and 47.5(b).

None.

Dated: November 8, 2019

By: /s/ Dominick A. Conde
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I. Introduction

The Court should deny Actavis's Petition for Rehearing and Rehearing En Banc. Written description involves a fact intensive analysis. Here the majority ruled that the District Court did not clearly err in its detailed written description fact findings. Actavis's attempts to make it seem like the majority's decision went beyond that conclusion and implemented new standards are misplaced.

First, Actavis fails to point out a key fact: that the '195 patent expressly permitted the use of dissolution methods "substantially equivalent" to the USP 2 method. Thus, after Actavis alleged that data generated using USP 1 should be ignored in analyzing written description, it is no surprise that the District Court evaluated whether USP 1 and USP 2 were substantially equivalent. Nor is it surprising that this Court evaluated whether the District Court clearly erred by finding them substantially equivalent. Thus, contrary to the petition, the majority did not create a new "substantial equivalent" standard, but rather applied existing precedent to the patent specification at issue.

Second, Actavis mischaracterizes this Court's precedent on written description. It argues that disclosure "equivalent" to a claim term cannot provide support for that term under § 112. But Actavis overlooks that its own cases state the opposite. *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). Actavis mistakenly argues that the majority erred by applying "different rules" for "different tiers of claim limitations" based on their importance to the invention. Here, the majority properly indicated that the "specific, positive steps" of treating obesity were the "operative" claim limitations, *i.e.*, involved the method of treatment. In contrast, the dissolution limitations were "non-operative" in that they reflected the dissolution profile of the composition administered in the method, not the method steps themselves. While the majority distinguished the two different types of claim limitations, it never stated either limitation could be ignored. Nevertheless, contrary to the petition, this Court has accounted for a limitation's relationship to the invention when assessing the adequacy of disclosure under § 112.

Third, while Actavis alleges that "unrebutted" evidence established that USP 1 and 2 were not substantially equivalent, it ignores the fact that the District Court discredited Actavis's evidence (*e.g.*, pointing out that Actavis's expert took positions that were at odds with one another), and credited the '195 patent's disclosure and Nalpropion's expert. Moreover, while Actavis's petition focuses on the prosecution history, Actavis failed to raise any written description argument based on a prosecution history disclaimer before the District Court. The Court can disregard Actavis's theory that a non-limiting USP 2 dissolution clause would

require remand because Actavis admits that the parties and Court agree that the USP 2 clause limits the claims.

II. Background

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, 799-800 (D. Del. 2017). It requires administering, twice daily, specific doses of sustained release formulations of two active ingredients (naltrexone and bupropion). *Id*. Actavis conceded that the inventors had possession of those elements. The claim further recites a dissolution profile for naltrexone, which Actavis alleged lacked written description support.

As to the dissolution profile, the District Court found that the specification sets forth dissolution data "falling squarely within the claimed 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 dispute that the specification discloses the claimed dissolution values, but rather took issue with the inventors' use of USP 1 rather than USP 2 to obtain some of the values. The District Court found that any differences between those methods were 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 POSA would

have understood the inventors possessed their invention regardless of whether they used USP 1 or USP 2 dissolution test. *Id.* It further found that 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 lack of written description. *Id.* at 803.

Actavis appealed the written description holding, which this Court affirmed. The majority deferred to the District Court's fact findings and credibility assessments, which credited Nalpropion's expert over the "untrustworthy, self-serving testimony by Actavis's expert," and concluded that the finding "does not present clear error." Op. at 10-11. The majority recognized 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.* at 11. It adhered to that "flexible, sensible" standard in concluding 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 11-12.

III. Argument

A. The '195 patent expressly permitted dissolution tests "substantially equivalent" to USP 1; the majority did not create a new written description rule.

Actavis argues that the majority created a new "substantially equivalent" rule. It did not. The "substantially equivalent" language came directly from the patent in question. Specifically, the '195 patent 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***.

Appx000182 (6:49-55) (emphasis added).

At trial, Nalpropion's expert testified that written description was adequate even if the USP 1 method was used to generate data disclosed in the specification that was relied on, 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 determined that there was 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).

* * *

> 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). And in analyzing written description, the District Court made plain that it was applying this Court's precedent set forth in *Ariad*. *Id.* at 800.

On appeal, the majority 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.'" Op. at 11. The majority deferred to the District Court's fact findings and credibility assessments regarding whether the two methods were substantially equivalent, 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.

Op. at 10-11.

Thus, there was nothing remarkable about the District Court's application of precedent, nor the way that the majority analyzed whether there was clear error. And, no "new rule" was created. To the contrary, the majority, following this Court's precedent, reviewed evidence relied on by the District Court and concluded that based on the patent specification and fact-finding "***in this case"*** there was no clear error. Op. at 12 (emphasis added). In short, the majority simply applied existing precedent to the facts.

B. The Decision is squarely within this Court's precedent, and it does not create any new legal standards.

1. The majority's "flexible, sensible" approach accords with precedent.

Actavis asserts that the majority contravened *Lockwood*, *Ariad*, *Vas-Cath*, and *Lucent* by replacing a "bright-line" rule with a "flexible" test whereby "equivalent" disclosure can support claims. Pet. at 1, 3, 14. Actavis

mischaracterizes the law— each of those decisions accords with the majority's analysis and lends no support to Actavis's argument.

In *Lockwood*, the Court made clear that the specification need only contain an "***equivalent description***" of the claimed subject matter. 107 F.3d at 1572 (emphasis added); *see, e.g., Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1347 (Fed. Cir. 2016) (written description requirement met for claim terms not in specification where "patentee used different words to express similar concepts"), quoting *Innova/Pure Water, Inc. v. Safari Water Filt. Sys., Inc.*, 381 F.3d 1111, 1120 (Fed. Cir. 2004). Despite heavily relying on *Lockwood*, Actavis's petition omitted this key language from *Lockwood*.

In *Ariad*, the Court ***rejected*** bright-line rules. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) ("[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 . . ."). Actavis's other authority also eschewed bright-line rules. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 928 (Fed. Cir. 2004) (acknowledging that "applicants have some flexibility in the 'mode selected for compliance' with the written description requirement."). Actavis identifies no case endorsing the unspecified "bright-line" test that the majority supposedly "replaced." Pet. at 3.

In *Vas-Cath*, the Court similarly rejected "[r]igidity" (Op. at 12), ***reversing*** summary judgment of invalidity, and "stress[ing] 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 Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991) (emphasis original) (citations and quotation marks omitted). That is what the District Court did here, analyzed written description based on the facts, and the majority concluded that there was no clear error.

The Court in *Vas-Cath* further recognized that an applicant "does not have to describe exactly the subject matter claimed," and that "ranges found in applicant's claims need not correspond *exactly* to those disclosed in" the specification. *Id*. at 1563, 1566 (emphasis original), citing, *inter alia*, *Ralston Purina Co. v. Far-Mar-Co, Inc*., 772 F.2d 1570, 1575 (Fed. Cir. 1985). *Ralston* mirrors the majority's "flexible, sensible" approach in this case. Op. at 12. The Court there found written description adequate for certain claimed ranges even though the specification did not disclose the exact ranges. 772 F.2d at 1575-77.

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 *Rochester* and *ICU* fails for similar reasons. In *Rochester*, the Court found inadequate support for use of new COX-2 inhibitors that the inventors merely "hypothesized" might exist. 358 F.3d at 923. Actavis does not dispute that the USP 2 and USP 1 dissolution methods existed prior to the filing of the '195 patent. In *ICU Medical, Inc. v. Alaris Med. Sys., Inc*., 558 F.3d 1368, 1378 (Fed. Cir. 2009), the Court 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." Here, the specification states that the inventors obtained dissolution data using USP 2 or "substantially equivalent" methods, and discloses dissolution data generated using USP 2 and USP 1. *Orexigen*, 282 F. Supp. 3d at 801-02.

2. The standard for sufficiency of disclosure depends on a limitation's relationship to the invention.

Actavis criticizes the majority for purportedly lowering the § 112 standard for a limitation that "relates only to resultant dissolution parameters rather than

[an] operative . . . step[]" (Op. at 12) 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 9-10, 12 (emphasis original). But while one overarching standard is applied, Actavis fails to acknowledge that the underlying facts dictate the sufficiency of disclosure.

The majority did not apply a different legal standard to the different types of claim limitations. Rather, the majority stated that some of the claim limitations were directed to "specific, positive steps of administering a formulation" (operative steps), and other limitations were directed to the "dissolution profile" of that formulation (non-operative step). Op. at 10. Its written description analysis took those factual differences into account, as is dictated by this Court's precedent.

In *Ariad*, the 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 1351-52 (emphasis added). For example, 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 standard governing 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 majority's analysis of the "non-operative" dissolution limitation parallels the standard applied in *Ariad*, *Herschler*, and *Fuetterer*, recognizing that the written description requirement "depend[s] on the nature and scope" of the claim term. The '195 patent claims a new method of treating obesity—not a novel dissolution method or apparatus—and the majority correctly accounted for that when finding adequate written description support for the dissolution profile.[1]

[1] The amicus curaie's focus on the purportedly "functional" nature of the dissolution limitation (DE 99 at 7) fails to distinguish, *e.g*., *Herschler* and *Fuetterer*, because the limitations at-issue there were at least as "functional" as the dissolution limitation here. The claims in *Herschler* required "effectively enhanc[ing] penetration of [a] steroidal agent to achieve [a] desired physiological effect." 591 F.2d at 695. The claims in *Fuetterer* required a salt that would maintain a mixture in colloidal suspension to improve the traction of tires on wet pavement. 319 F.2d at 260-61.

C. Actavis mischaracterizes the record and the majority's opinion.

Actavis's remaining arguments rely on incorrect interpretations of the record and the majority's decision.

1. The majority did not conflate written description and obviousness, nor did it fail to explain what constitutes a "non-operative" limitation.

Actavis argues that a disclosure that merely renders a claim obvious does not provide written description support for that claim. Pet. at 10-12. But neither the District Court nor the majority held that an "obvious variant[]" of USP 2 provided written description support for the dissolution limitation. *Id*. at 12. The majority mentioned obviousness only to explain its deference to the District Court's finding that Actavis's expert lacked credibility in view of the inconsistency between: (1) his "theoretical" opinion (unsupported by any data) that USP 1 and 2 would yield different results in the written description context; and (2) his opinion that USP 1 data rendered obvious the USP 2 limitation. Op. at 11.

Actavis also wrongly criticizes the majority for failing to set forth guidance on what constitutes a "non-operative" limitation (Pet. at 3, 14). The majority did not discuss "operative" and "non-operative" limitations in the context of a new standard requiring guidance. Rather, the majority made clear that for the claims at issue some limitations related to a step in the method of treatment (operative

limitation) and other limitations related to dissolution data for 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.

Op. at 10 (emphasis added). And the dissent did not take issue with the majority's use of "operative." Dissent at 2 ("The majority and I agree that the essence of the claimed invention is 'a method of treating overweight or obesity.' We also 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).

2. The Court should reject Actavis's attempt to re-litigate the case.

Actavis dismisses *Lockwood*'s *in hac verba* language in a footnote because allegedly "unrebutted" evidence established that USP 1 and USP 2 would have produced different results. Pet. at 12 n.4. But the District Court discredited Actavis's only evidence of differences. 282 F. Supp. 3d at 801-02 ("[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*, 772 F.2d at 1573-74. Actavis now tries to bolster its expert's discredited testimony with evidence outside the record. It cites for the first time a Youtube video on USP 1 and 2. Pet. at 4 n.1. That video published after the priority date of the '195 patent and thus would not salvage Dr. Mayersohn's discredited opinion, even if it were properly before the Court. In any event, Actavis ignores the evidence that the District Court credited in finding the distinction between USP 1 and USP 2 inconsequential: (1) the '195 patent's statement that "all of the dissolution data reported in the patent was obtained 'using [USP] 2 . . . or other test conditions substantially equivalent thereto'"; and (2) Nalpropion's expert testimony that a POSA would have understood the inventors possessed their invention regardless of whether they tested dissolution with USP 1 or 2. *Orexigen*, 282 F. Supp. 3d at 801-02 (citation omitted); *see also* Appx011410 (656:14-22), Appx011411-011412 (657:23-658:9), Appx011416-011417 (662:20-663:4).

In addition, Actavis alludes to arguments made during prosecution of the '195 patent (Pet. at 5-6, 17), but does not contend that applicants disclaimed non-USP 2 dissolution data. Nor could it. Actavis did not advance any prosecution history disclaimer argument based on the USP 2 limitation during *Markman* proceedings. And Actavis never asserted before the District Court that claim 11 lacks written description in view of a prosecution history disclaimer. Regardless,

applicants did not disclaim "substantially equivalent" methods because they expressly identified examples using those methods (including USP 1) as support for claim 11 when they amended it to recite USP 2. DE 35 at 25; Appx007037.

Finally, Actavis argues that ***if*** the majority ruled that the USP 2 dissolution term does not limit the claims, then the Court should "remand[] for further proceedings consistent with that new construction." Pet. at 17. But, Actavis admits that the parties, District Court, and majority agree that the USP term limits the claims. *Id.* The Court therefore need not consider this argument. And Actavis's insinuation that claim 11 would be invalid under §§ 102 or 103 if the USP 2 term were non-limiting amounts to nothing more than conjecture. Actavis elected not to raise these arguments at trial. The Court should disregard its belated attempts to disparage the invention with attorney argument about "known" ingredients and references that the Patent Office considered before allowing the claims. Pet. at 3, 16-17.

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

Actavis's discussion in passing regarding "generic [drug] competition" (Pet. at 3), is the domain of Congress, not the judiciary. Even if this were the proper forum for Actavis's concerns, the facts here do not warrant revisiting "continuation practice" and redefining the patent term to increase generic competition. Pet. at 15. The holding here turned on a credibility assessment concerning alleged

differences between dissolution data generated using a known USP 1 method and a known USP 2 method.

Actavis's own actions belie its amicus's concerns that the majority's decision will dissuade generic companies from designing around the '195 patent. DE 99 at 13. Actavis generated the infringing dissolution profile, rather than designing around the invention, ***before*** the majority's decision. *Orexigen*, 282 F. Supp. 3d at 816 ("[Actavis] does not appear to dispute that some of the tablets it tested fall squarely within the claimed dissolution profile.").

IV. Conclusion

For the foregoing reasons, the Court should deny Actavis's Petition for Rehearing and Rehearing En Banc.

Dated: November 8, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME, TYPE-FACE AND TYPE-STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Circuit Rule 35(e)(4) because it contains 3,885 words, excluding the parts of the brief exempted by Federal Circuit Rule 35(e)(4).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word 2016.

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