Appeal No. 18-1221

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

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

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October 30, 2019

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Association for Accessible Medicines certifies:

1. The full name of every party or amicus represented by me is:

Association for Accessible Medicines

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

See above.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the amicus curiae represented by me are:

Not applicable.

4. The names of all law firms and the partners or associates that appeared for the amicus curiae 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:

Not applicable.

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 is:

None.

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INTEREST OF THE *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 22% of total drug spending. AAM regularly participates in litigation as *amicus curiae*. Pursuant to Fed. R. App. P. 29(b)(3), AAM files contemporaneously herewith its unopposed motion for leave to file this amicus brief.

AAM and its members have a significant interest in the issues raised by Appellant's petition for rehearing and rehearing *en banc*. As Appellant's

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1 No counsel for any party authored this brief in any part, and no party, counsel, or person other than AAM, its members, and its counsel contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

petition ably explains, the panel majority's decision weakens and confuses the written description requirement. Under the panel's opinion, a patentee may expand patent coverage beyond its disclosed invention to reach undefined "substantial equivalents" for an ambiguous set of "resultant parameter" claim limitations. *See* D.I. 77, Slip op. at 10, 12. Yet the panel's decision provides no test for determining "substantial equivalence;" it does not clearly define the kinds of claim limitations that qualify for this less-exacting treatment under written description law; and it certainly does not justify as a matter of law (or policy) the imposition of an amorphous two-tier system for evaluating the adequacy of the written description that contradicts entire lines of established Federal Circuit authority. *See* D.I. 85, Actavis Pet. at 10-11 (reviewing three opinions, plus the *en banc* ruling in *Ariad*, with which the new standard conflicts).

This "problematic[] . . . new rule for written description," Slip op., dissent at 5, is of particular concern to AAM and its members. Generic and biosimilar manufacturers seeking to develop competing alternatives to expensive brand-name drugs already face substantial and well-documented challenges from large patent estates. *See, e.g.*, Biosimilars Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's*

Patients at 5-7 (June 2019).[2] The panel's amorphous "substantial equivalence" standard now threatens to give drug company patentees license to expand their patent portfolio to cover competing products they *never invented*, including design-around generic alternatives to high-priced pharmaceuticals.

This new freedom to claim broadly is particularly troubling in the context of continuation applications claiming variations of a drug claimed in a parent application. A patentee seeking new claims to cover competing products can allege "substantial equivalence" to sidestep the new matter prohibition and maintain the parent application's priority date, barging in front of the new product and defeating intervening would-be prior art. *E.g.*, *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004); *see also* 35 U.S.C. § 120. The ultimate victim of these tactics will be patients, who will be deprived of cost-saving generic alternatives that were never conceived of by patentees.

A rule that deprives the public of the complete invention disclosures to which it is entitled—while simultaneously stifling good faith-efforts to

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2 *Available at* https://www.biosimilarscouncil.org/wp-content/uploads/2019/06/Biosimilars-Council-White-Paper-Failure-to-Launch-June-2019.pdf.

develop competing products—disserves the purpose of the written description requirement. AAM respectfully urges the Court to grant rehearing to restore written description to its role of ensuring "that the inventor actually invented the invention claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

ARGUMENT

I. The Majority Ruling Contravenes Precedent.

There is a well-established bargain underlying the written description requirement: before the patent claims may take, the written description must give. *E.g.*, *Ariad*, 598 F.3d at 1353-54 (explaining that written description "ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time"). To preserve this balance, written description demands that "what is claimed by the patent application must be the same as what is disclosed in the specification." *Id.* at 1346-47.

Here, however, the panel majority adopted a "flexible" approach to written description that permits the patentee to claim an undisclosed obvious variant—termed a "substantial equivalent" in this case—of its alleged invention. Slip op. at 12. The panel's approach contravened

numerous decisions of this Court—both panel and *en banc*—recognizing that obvious variants do not suffice for written description. *See* Actavis Pet. at 10-11 (discussing four cases rejecting "obvious variant" theory); Slip op., dissent at 5-6 (noting subset of same). They do not suffice for a straightforward reason: the patentee never had possession of what is actually claimed. *See, e.g.*, *Ariad*, 598 F.3d at 1352.

In this case, the question before the Court is whether the patentee could claim a naltrexone dissolution profile as measured by a measurement technique called the "paddle method," when the key portion of the written description disclosed only data measured by a separate technique called the "basket method." *See* Slip. op. at 6, 9. While acknowledging that "as a general matter written description may not be satisfied by so-called equivalent disclosure," the majority here excused the patent's failure to disclose any invention of a naltrexone formulation exhibiting the claimed dissolution profile. Slip op. at 12. The majority justified doing so on the ground that the disclosed basket method was "substantially equivalent" to the claimed paddle method, opining that "[r]igidity should yield to flexible, sensible interpretation." Slip op. at 10, 12.

But "substantial equivalence" is no substitute for disclosure of the actual claimed invention. If an obvious invention does not satisfy the written description requirement, *Ariad*, 598 F.3d at 1352, then a substantially equivalent invention does not either. No matter how great or small the differences between the disclosed invention and the claimed subject matter, a patentee may properly claim only what the patentee actually invented. As *Ariad* explained, "a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent." *Id.* Indeed, in language that could (and should) have been used in this case, this Court has decried, as "exactly the type of overreaching the written description requirement was designed to guard against," a claim for a method of treatment using an extended release drug having "a characteristic that is not discussed even in passing in the disclosure." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1327 (Fed. Cir. 2000).

Finally, although the panel seemed to believe that it could depart from these precedents because it considered the claimed dissolution profile to be a mere "resultant . . . parameter rather than operative claim step," Slip op.

12, that supposed distinction does not justify the panel's newly-crafted rule. There is no exception in written description law for claims directed to "resultant parameters," and the majority never explains why this should matter. To the contrary, the dissolution profile claimed here is essentially a functional claim limitation—it covers any naltrexone formulation exhibiting the claimed dissolution profile without specifying what type of formulation will exhibit that profile. If anything, precise written description is most needed for such a limitation. *Ariad*, 598 F.3d at 1349 (with respect to "genus claims that use functional language" to "simply claim a desired result . . . without describing species that achieve that result," deeming "especially acute" the need for the written description to "show[] that the applicant has invented species sufficient to support a claim to the functionally defined genus").

Worse still, the majority offered no guidance on how to identify such second-class "parameter" limitations. Here, the panel chose to segregate the claimed dissolution profile from the "operative" administration steps in the claim. Slip op. at 10. But, as the dissent observed, the dissolution profile is an integral part of an administration step, *i.e.*, the step of administering a naltrexone formulation having the specified extended release profile. Slip

op., dissent at 2-3. The dissolution profile provides the only definition of the drug that is to be administered—without it, there is nothing to administer. The panel viewed the claimed dissolution profile as less deserving of adequate written description on the basis of an arbitrary claim parsing exercise.

II. The Majority's "Flexible" Approach to Written Description Will Hinder Innovation and Competition, Particularly For Generic Alternatives.

The majority's amorphous new standard is not just at odds with this Court's precedents, it also will dramatically curtail both pharmaceutical innovation and competition — thus defeating the purpose of the patent system to "promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8.

A. Patentees Will Be Incentivized to Disclose Incomplete Inventions.

The majority's standard will encourage either truncated disclosure of an invention or incomplete innovation in the first instance. The specification is "highly relevant" and oftentimes "dispositive" with respect to claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). With no requirement that the specification disclose a particular claim element, a patentee—already freed under the AIA from a penalty for failing

to disclose its best mode—might choose to omit from its written description any discussion that might narrow its claims.

As a result, the public will not receive a full teaching of the invention, and the patentee may secure overly broad claim scope—an outcome the written description requirement is supposed to guard against. *See Ariad*, 598 F.3d at 1353 ("[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'").

Alternatively, a patentee that no longer needs to demonstrate possession of the entire claimed invention may stake an early priority date by leaving its invention unfinished while still acquiring broad claim coverage through "equivalent" disclosures. But the written description requirement is meant to "prohibit[] a patentee from leaving it to the industry to complete an unfinished invention." *Novozymes A/S v. DuPont Nutrition Bioscis. APS*, 723 F.3d 1336, 1350 (Fed. Cir. 2013) ("A patent, however, 'is not a reward for the search, but compensation for its successful conclusion.'") (internal modifications omitted). Again, under the panel majority's approach, the public would be deprived of a complete invention. *See Ariad*,

598 F.3d at 1353 ("Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of 'invention'—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public.").

The patent here is emblematic of these concerns. Although the majority relegates the claimed dissolution profile to the status of a mere "resultant parameter," Slip op. at 10, 12, the profile was central to allowance of the claim. *See, e.g.*, Slip op., dissent at 3-4 (reviewing the "material role" of the dissolution profile during prosecution). Indeed, this claim is the only one still standing in this case because Appellant successfully invalidated as obvious the other claims at issue. Slip op. at 21-22. So the undisclosed, never-invented dissolution profile is effectively the only reason weight-loss patients presently have no generic option for the naltrexone-bupropion extended release drug at-issue here.

B. Patentees Will Be Incentivized to Claim Design-Arounds That They Did Not Invent.

The written description requirement under the panel's decision will cease to fulfill another key function: "prohibit[ing] new matter from entering into claim amendments, particularly during the continuation process." *See, e.g.*, *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir.

2009). Even if not actually disclosed in the specification, a patentee can secure patent claims in a continuation application directed to a competitor's later design-around by arguing that it disclosed a "substantial equivalent" in the written description. Particularly in the pharmaceutical field, where regulations require bioequivalence or biosimilarity and, thus, limit the extent to which a generic or biosimilar manufacturer can deviate from a patented drug (*e.g.*, 21 C.F.R. § 314.94(a)(7)), the "substantial equivalent" standard grants the patentee ample opportunity to capture design-around efforts through continuation practice. *See* Actavis Pet. at 15-16.

These problems are not ameliorated by the majority's assertion that its relaxed written description rule is directed to "substantial equivalents" for claim limitations that recite "resultant parameters." Slip op. at 10, 12. The majority provides no definition or test by which to determine whether a disclosure is a substantial equivalent, and never explains why resultant parameters—along with perhaps other types of claim elements—deserve different treatment. Not only will the specter of a broadened continuation claim loom over a generic manufacturer considering a design-around product, but the majority opinion provides the generic manufacturer with no guidance as to just how far afield a continuation claim may stretch a written

description to capture a product. As a result, the manufacturer may refrain from pursuing the design-around at all, to the detriment of competition in the marketplace. *See Ariad*, 598 F.3d at 1353 (noting that the written description requirement provides "the incentive to actual invention and not attempts to preempt the future before it has arrived" (internal quotations omitted)).

The uncertainty facing a generic or biosimilar manufacturer is particularly stark if it cannot rely on the patent's intrinsic record to assess written description. Written description should be assessed based on the four corners of the specification. *Ariad*, 598 F.3d at 1351. But here, for example, extrinsic expert testimony as to the alleged equivalence between the paddle and basket methods played a central and polarizing role, with the district court and panel majority reaching the opposite conclusion than did the dissent. *Compare* Slip op. at 11-12, *with* dissent at 6-7. So even if a generic manufacturer chooses to pursue a design-around, the vague concepts of "substantial equivalence" and "resultant parameter" limitations—left undefined by the panel majority—will require lengthy and uncertain litigation, pending while the generic company remains subject to a statutory stay of regulatory approval. *See, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii).

Consider again the extended release medication at issue here. Before the majority's new rule, the patentee would have been limited to claiming the dissolution profile (measured by the basket method) disclosed in the specification. *Cf.* Slip op., dissent at 5-6. A generic competitor could design around this patent by, say, developing a drug exhibiting a superior dissolution profile as measured by the paddle method. But under the new rule, the competitor would be dissuaded from investing resources for such an advance in patient treatment because of the risk that the patentee will claim the superior profile in a continuation patent, justifying the new claim as simply covering an equivalent of the disclosed dissolution profile. Given the amorphous nature of the panel's rule, the competitor would have no way of assessing whether a fact-finder might deem the two profiles "substantially equivalent." For a manufacturer looking to develop a competing generic product, an undefined notion of "substantial equivalence" is particularly concerning.

In sum, under the majority's new standard, written description will fail to ensure the public's right to knowledge of an invention while also discouraging design-around competition. The new standard should not be allowed to persist.

CONCLUSION

AAM respectfully requests that the Court grant Appellant's petition for rehearing.

Respectfully submitted,

Dated: October 30, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on October 30, 2019, I caused the foregoing brief to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system, which caused a copy of the foregoing to be delivered by electronic means to counsel of record.

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This Brief complies with the type-volume limitation of Fed. R. App. P. 29(b)(4) because this Brief contains 2,596 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b).

2. This Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this Brief has been prepared in a proportionately spaced typeface using Microsoft Office Word 2013 in Century Expanded LT Std, Font Size 14.

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