

In the Supreme Court of the United States

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HZNP FINANCE LIMITED,  
HORIZON THERAPEUTICS USA, INC.,

*Petitioners,*

v.

ACTAVIS LABORATORIES UT, INC.,

*Respondent.*

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On Petition for A Writ of Certiorari to The United States  
Court of Appeals for The Federal Circuit

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**REPLY BRIEF FOR THE PETITIONER**

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## ARGUMENT

The issue on appeal is novel and important: whether the “basic and novel properties” of an invention must contain “objective boundaries” pursuant to *Nautilus* and the written description requirement of 35 U.S.C. § 112. Prior to this case, neither the Patent Office nor the courts had *ever* evaluated the “basic and novel properties” of an invention for definiteness. This is because “basic and novel properties” are not claim elements. Rather, they are part of the description of the invention set forth in the patent specification. Until this case, the Patent Office and the courts only looked to “basic and novel properties” as part of the factual evaluation of infringement or validity, where the patent claims recited “consisting essentially of” and where the prior art or accused product included an additional unclaimed element or ingredient. “Basic and novel properties” were never “incorporated” into the claims as functional claim requirements or viewed as defining the claim scope.

Actavis does not legitimately contest that the issue on appeal is novel or important, or that, if allowed to stand, the Federal Circuit’s decision has the potential to undermine the validity of the many thousands of pending and granted patents employing the “consisting essentially of” phrase. Instead, Actavis attempts to recast the issue on appeal as a “fact-bound decision,” which it is not, and incorrectly asserts that “unchallenged findings” compel a finding of indefiniteness under the current law, despite the fact that there is *no prior decision* that compels such a conclusion. Actavis also suggest that there is no split of opinions, when clearly there is, as evidenced by the fact that four judges on the Federal Circuit dissented and former Chief Judge

Michel of the Federal Circuit has written separately to urge this Court to review the panel majority's new rule.

Clarity in the patent law is critical to protecting current and future innovation in this country. We respectfully urge this Court to restore clarity to the application of Section 112 of the Patent Act to claims containing the transitional phrase "consisting essentially of."

**I. The Panel Majority's Decision Will Have Far Reaching Impacts on the Patent Office and the Courts if Allowed to Stand Because It Is Not Limited to Its Facts**

Actavis contends the panel majority's decision does not warrant review because it is a "fact-bound decision" limited to a "particularly idiosyncratic" set of facts. (Actavis Brief at 1.) This is without merit.

Horizon does not appeal the factual findings underlying the finding of indefiniteness of the term "consisting essentially of." Horizon does not contest the district court's identification of the five "basic and novel properties" as including improved drying time, and Horizon does not contest the court's ruling that the *actual* claim limitation specifying a particular "drying rate" is indefinite. Horizon only appeals the Federal Circuit's finding that the claim phrase "consisting essentially of" is indefinite because the "basic and novel property" of improved drying time is indefinite. This is purely a legal issue.

With respect to this legal issue, Actavis does not dispute that many *thousands* of pending and issued patents use the transitional phrase "consisting essentially of" in reliance on the decades of jurisprudence allowing identification of "basic and novel

properties” without a requirement that there be objective boundaries to satisfy Section 112. Actavis merely attempts to downplay the impact of the panel’s decision by asserting that “the Patent Office and the courts have been applying the definiteness requirement to all claims and all claim terms for over two centuries, apparently without any undue difficulty.” (Actavis Brief at p. 23.) Actavis misses the mark. Horizon agrees that both the Patent Office and the courts “have been applying the definiteness requirement *to all claims and all claim terms* ... without any undue difficulty.” But now, for the first time, a court has applied the definiteness requirement to “basic and novel properties.”

Actavis ignores that the Federal Circuit’s decision has changed and improperly expanded the law of Section 112. The issue on appeal is that, prior to the district court’s decision, no court had *ever* evaluated the “basic and novel properties” of an invention, as described in the patent specification, for definiteness under Section 112. Indeed, the panel majority held, for the first time, that each “basic and novel property” of an invention claimed using the transitional phrase “consisting essentially of” *must* be defined with objective boundaries as if such properties are actual recited claim limitations. Patent applicants have never before had any notice that “basic and novel properties” of an invention may be viewed as claim limitations. The Patent Office does not currently provide *any* guidance in the Manual of Patent Examining Procedure (MPEP) regarding evaluation of *the “basic and novel properties”* for definiteness. So, while Actavis tries to argue that “[t]he majority’s

holding . . . is hardly likely to spawn the parade of horrors set forth in the petition” because it is limited to its particular facts (Actavis Brief at 23), this is clearly false.

Indeed, the Federal Circuit’s 8-4 split was a disagreement over the law, not facts. Rather, Judge Lourie, Newman, O’Malley, and Stoll issued a strongly worded dissent urging that this new rule was of “broader importance” than the issue at hand. Appx. 99. And recently, former Chief Judge of the Federal Circuit, Paul Michel, published a detailed analysis urging that Supreme Court review is necessary to correct the panel majority’s mistake. *High Court Should Review Horizon Arthritis Drug Patent Case*, Law360 (Sept. 8, 2020). Judge Michel warned that the panel majority’s decision will cause “greater harms to public notice and the patent system” resulting from “(1) deciding claim indefiniteness based not on any claim language, but on properties incorporated from the specification; and (2) casting a judicial pall on the definiteness of a claim term, ‘consisting essentially of,’ that for decades had an established legal meaning — one that patent stakeholders understood and relied on.” *Id.* Judge Michel explained that the decision was also legally erroneous because it ignores the fundamental axiom of patent law that “claims claim” and “the specification teaches,” it applies an “incorporation theory” as to the “basic and novel properties” which “runs afoul of the long-standing principle that courts ordinarily interpret claims ‘in light of the’ specification’s disclosure – not by ‘incorporating it,’” and it violates the principle (recognized by the Supreme Court) that underlying fact questions should not render claims indefinite. *Id.*

The factual record in this case, while not at issue on this appeal, serves to illustrate how the panel majority’s decision, if left unchanged, will facilitate complex and unnecessary challenges to patent validity whenever the phrase “consisting essentially of” is used. Indeed, the Horizon claims at issue do not recite a specific “drying time.” Actavis’s accused product does not contain any additional unclaimed ingredients. And no additional ingredient (or its impact on drying time) was ever discussed or considered by the district court. There was no fact question ever presented to the district court that required it to evaluate “drying time” in connection with the “consisting essentially of” claims. The facts relied upon by the district court relating to the property of “drying time” were derived entirely from the specification and related to a different formulation – the F971 gel formulation – that has little relation to the Actavis accused product. Had the Actavis accused product included an additional ingredient beyond those claimed, such that evaluation of its impact on “drying time” was required, the facts may very well have shown that such additional ingredient produced a consistent change in “drying time” under both tests described in the specification, such that there was no ambiguity as to the fact question of infringement.

Under the panel majority’s new rule, it does not matter whether there are even additional ingredients at issue that might affect a basic and novel property. Regardless, each basic and novel property is subject to an indefiniteness analysis, in a vacuum, that could render the property, and thus the claim, indefinite. If allowed to stand, accused infringers will begin to routinely use the panel majority’s decision



to attack every “consisting essentially of” claim moving forward. So long as an accused infringer can find one “basic and novel property” that is identified in the specification as a general property, rather than with “objective boundaries” and a uniform method for determining whether those boundaries may be met, the claims may be found invalid.

## **II. The Panel Majority’s New Rule Is Not Supported by the Cited Legal Precedent**

According to Actavis, the Federal Circuit’s decision in *PPG Industries* confirmed that the definiteness requirement applies to the claim phrase “consisting essentially of.” (Actavis Brief at 13.) This is incorrect. The court in *PPG Industries* merely held that the transitional phrase “consisting essentially of” contains some inherent imprecision that can be resolved by the trier of fact during the validity or infringement factual inquiry. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354-55 (Fed. Cir. 1998). The court in *PPG Industries* never held that the “basic and novel properties” of the invention are incorporated into the claims, transforming them into claim limitations that are subject to the definiteness requirement of § 112. Indeed, in *PPG Industries*, the court identified the “basic and novel properties” of the claimed glass invention as “color, composition, and light transmittance,” but the court did not consider whether these three properties were indefinite. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Actavis next argues that “[i]n a ‘consisting essentially of’ claim, the basic and novel properties themselves define the scope of the invention,” and therefore, Actavis asserts that *Nautilus* supports that “the basic and novel properties . . . incorporated

in such a claim must also satisfy § 112.” (Actavis Brief at 13.) But it is not accurate to state that “the basic and novel properties themselves define the scope of the invention.” *Id.* Indeed, there is no court precedent for such a conclusion. Rather, as detailed in Horizon’s Petition, basic and novel properties have always been used as tools to evaluate whether the addition of an additional component to the claimed invention avoids infringement or whether the inclusion of an additional component in a prior art composition renders the claimed invention invalid.

Actavis’s own proposed hypothetical, as applied to the particular claims at issue, illustrates the error in Actavis’s analysis of the legal precedent. (Actavis Brief at 14.) Actavis describes a claimed composition “consisting essentially of” ingredients 1, 2, and 3 as defined by the claims. Clearly, a composition containing only ingredients 1, 2, and 3 would infringe this hypothetical claim regardless of its “drying time.” Thus, the basic and novel property of “better drying time” cannot be said to “define the scope of the invention,” as in the case where a composition does not contain any additional ingredient, the drying time of that composition would not need to be evaluated at all. However, under the panel majority’s new rule, even though “better drying time” was not at issue because no additional ingredients were in dispute (as was the case here), the claim could still be found invalid if there were not a uniform method or “objective boundaries” described in the specification as to the “basic and novel property” of “better drying time.”

Moreover, Actavis’s hypothetical also illustrates the complications that result when requiring a court or the Patent Office to evaluate the definiteness of a “basic

and novel property” in a vacuum, rather than in the context of a specific piece of prior art or a specific accused product. In the instance where the accused composition contains an additional ingredient 4, it does not necessarily follow that the trier of fact would require a uniform method or “objective boundaries” described in the specification to determine whether the additional ingredient 4 materially affected the “basic and novel property” of “better drying time.” Ingredient 4 could be an ingredient that every scientist understands to significantly alter “drying time” (either by speeding it up or slowing it down). But in that case, even where no method of measuring would be necessary to determine whether adding ingredient 4 into the formulation avoids infringement, the claims could still be found invalid.

Actavis’s solution to the problem that the panel majority has now created is to assert that Horizon could have used the transitional phrase “consists of” instead of “consisting essentially of.” (Actavis Brief at 16-17.) But to read the panel majority’s decision as extinguishing the use of the more flexible transitional phrase “consisting essentially of” is problematic. This term has always played a critical role in the pharmaceutical industry, where pre-existing knowledge regarding the functions of additional ingredients allows companies to understand what additional ingredients would or would not avoid infringement, so long as the “basic and novel properties” are identified. It has never been necessary that the specification identify “basic and novel properties” in terms of objective boundaries as if they are required claim limitations.

### **III. Actavis Mischaracterizes Horizon’s Position and the Factual Record to Distract From the Significance of the Panel Majority’s New Rule**

Without a legitimate response as to the significance of the panel majority’s new rule, Actavis resorts to mischaracterizing the facts and the law. First, Actavis asserts that Horizon no longer contests that at least one of the “basic and novel properties” of the claimed invention—“better drying time”—is indefinite. (Actavis Brief at 11.) While it is true that Horizon does not contest whether the separate claim term relating to “drying rate” is indefinite in this appeal, Horizon by no means agrees that the specification’s identification of “better drying time” as one of the “basic and novel properties” is indefinite. Indeed, the notion that a “basic and novel property” can be indefinite is precisely the issue on appeal.

Next, Actavis asserts that the panel majority decision should be affirmed because “there is no contrary authority” and that it is Horizon that seeks to overturn “decades of precedent” and have this Court “adopt a sweeping rule.” (Actavis Brief at 11.) This is misleading. The facts are that until the district court in this case, no court had *ever* found the term “consisting essentially of” to be indefinite, or even considered whether it is indefinite, despite seven decades of jurisprudence, and to the contrary it has been accepted to have a well-established legal meaning. Horizon does not assert that “consisting essentially of” can never be indefinite. Rather, Horizon contends that the “basic and novel properties”—which are not themselves claim limitations, but rather tools for evaluating whether additional ingredients are allowed or disallowed—cannot be indefinite. The notion that “basic and novel properties” must have “objective boundaries” is a concept that was entirely fabricated by Actavis below,

and has never been stated by any court or authority in the history of U.S. patent law prior to this case.

Actavis further offers misleading statements regarding Horizon's prosecution of its patents. Specifically, Actavis argues that Horizon was "forced by the Patent Office to narrow its claims" from "comprising" claims to "consisting essentially of" claims to overcome prior art rejections and that Horizon now "wants to eat its cake and have it too." (Actavis Brief at 18.) This is plainly wrong and distracts from the importance of the issue at hand. It is undisputed that Horizon also obtained "comprising" claims protecting its PENNSAID® 2% product that were found valid and infringed by the District Court and Federal Circuit and preclude Actavis's generic copy from launching until expiration of Horizon's patents. Thus, Horizon already won this litigation and is not trying to "eat its cake and have it too," as Actavis alleges. (*Id.*) Horizon only seeks review of its "consisting essentially of" claims because the panel majority's decision stands in stark contrast to many decades of prior jurisprudence. Given the strong dissent of four Federal Circuit judges, Horizon believes it is important that this Court have an opportunity to review and correct the panel majority's mistake before it manifests itself throughout the U.S. patent system, burdening the courts and the Patent Office.

Actavis also accuses Horizon of attempting to convert the legal question—identification of an invention's basic and novel properties—into a factual question. (Actavis Brief at 21.) This is false. Horizon's specification identified the five basic and novel properties that should be considered to evaluate infringement of Horizon's

“consisting essentially of” claims, and this is not disputed. For decades, this was sufficient, and courts would move onto the second, separate factual step, determination of infringement. As Actavis admits, under the guidance of *PPG Industries*, once the basic and novel properties are identified, “the question whether the addition of an ingredient in the accused product materially affects one of the basic and novel properties of the invention is a factual question relating to infringement.” (Actavis Brief at 20.)

The Federal Circuit’s decision in this case eschews, without any legal authority, the decades-old practice of reserving “basic and novel properties” for the factual question of infringement and, in so doing, creates a new legal attack on patents employing the transitional phrase “consisting essentially of.” If permitted to stand, the court’s ruling will cast doubt over the validity of thousands of issued patents spanning technologies ranging from lifesaving medicines to innovative software code. Horizon respectfully requests that this Court review the Federal Circuit’s change of law to ensure that patent owners will have clarity going forward concerning the legal requirements for using “consisting essentially of” claims.

## **CONCLUSION**

For the reasons presented above, petitioners respectfully request that this petition for a writ of certiorari be granted.

Respectfully submitted,

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