

2017-2149, -2152, -2153, -2202, -2203, -2206

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

HZNP FINANCE LIMITED, HORIZON THERAPEUTICS USA, INC.,

Plaintiffs-Appellants

v.

ACTAVIS LABORATORIES UT, INC.,

Defendant-Cross-Appellant

**Appeals from the United States District Court for the
District of New Jersey in Nos. 1:14-cv-07992-NLH-AMD, 1:15-cv-05025-NLH-
AMD, 1:15-cv-06131-NLH-AMD, 1:15-cv-06989-NLH-AMD, 1:15-cv-07742-
NLH-AMD, 1:16-cv-00645-NLH-AMD, Judge Noel Lawrence Hillman**

**ACTAVIS'S RESPONSE TO HORIZON'S
PETITION FOR REHEARING EN BANC**

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Dated: December 20, 2019

**UNITED STATES COURT OF APPEALS FOR
THE FEDERAL CIRCUIT**

HZNP FINANCE LIMITED V. ACTAVIS LABORATORIES UT, INC.

Nos. 2017-2149, -2152, -2153, -2202, -2203, -2206

AMENDED CERTIFICATE OF INTEREST

Counsel for Cross-Appellant Actavis Laboratories UT, 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
Actavis Laboratories UT, Inc.	Not applicable.	Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd.

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:

Liza M. Walsh Christine I. Gannon Katelyn O'Reilly WALSH PIZZI O'REILLY FALANGA LLP Christopher J. Borchert (formerly with the firm) CONNELL FOLEY	Ralph J. Gabric Mark H. Remus Laura A. Lydigsen Joshua E. Ney, Ph.D. Joshua H. James Andrew S. McElligott Yun (Sophie) Wei, Ph.D. (formerly with the firm) BRINKS GILSON & LIONE
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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.

No appeal in or from the same civil actions in the lower court was previously before this or any other appellate court.

The following cases presently pending may directly affect or be affected by the Court's decision in this matter:

- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 1:16-cv-05051-NLH-AMD (D.N.J.)
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 1:16-cv-00732-NLH-AMD (D.N.J.)
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 1:15-cv-07745-NLH-AMD (D.N.J.)
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 1:15-cv-06935-NLH-AMD (D.N.J.)
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 1:15-cv-05027-NLH-AMD (D.N.J.)
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 15 cv-03051-NLH-AMD (D.N.J.)
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 1:17-cv-03342-NLH-AMD (D.N.J.)

December 20, 2019

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Everyone in this case agrees on the construction of the phrase “consisting essentially of”: it means that the claim covers compositions that contain (i) the listed ingredients and (ii) any other ingredients that do not materially affect the “basic and novel properties” of the invention. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003); Maj. Op. 22; Dissenting Op. 4; Horizon Pet. 2. The fundamental problem for Horizon is that is impossible to discern what ingredients would affect the “basic and novel properties” of the invention at issue here, so it is impossible to determine the scope of the claim.

Specifically, the district court concluded—in findings no longer challenged by Horizon—that at least two of the basic and novel properties of the claimed composition, “better drying time” and “favorable stability,” are indefinite because a skilled artisan would not know how to tell whether an additional ingredient would materially affect those properties. Maj. Op. 6–8. “Better drying time” is indefinite because the specification provides two different methods of measuring “drying time” that yield inconsistent results, and a skilled artisan would not know which method to use. *Id.* at 6–7. And “favorable stability” is indefinite because the specification links “stability” to the degradation of the formulation into “impurity A”—a term that (in another finding no longer challenged by Horizon) the district court also found to be indefinite. *Id.* at 5–8.

From these findings, it inexorably follows that the “consisting essentially of” claims in this case are indefinite. *Id.* at 32–33. If it is impossible for a skilled artisan to discern with reasonable certainty whether a given ingredient would “materially affect” the invention’s basic and novel properties, she would be faced with “a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909–10 (2014) (quoting *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942)). That is the very danger the definiteness requirement is designed to guard against. *See Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931).

Horizon’s petition for rehearing en banc takes (at 2) the incredible position that the claim term “consisting essentially of” can *never* be indefinite under 35 U.S.C. § 112 because it “is a legal term of art having a definite and well-established meaning.” That is a breathtakingly broad proposition, and it is flatly incorrect. *All* claim terms—including the transitional phrase “consisting essentially of”—must meet § 112’s definiteness requirement, so that the patent “afford[s] clear notice of what is claimed, thereby apprising the public of what is still open to them.” *Nautilus*, 572 U.S. at 909. The claims here do not meet that standard.

Horizon says (at 1) that it does not matter if the invention’s basic and novel properties are definite because those properties are not recited in the claim

language. But that is not the proper inquiry. The question is whether the basic and novel properties define the *scope of the invention*. See *Nautilus*, 572 U.S. at 910 (claims must “inform those skilled in the art about the scope of the invention with reasonable certainty”). The answer is yes. Under this Court’s long-standing precedent, the basic and novel properties dictate which additions to the claimed composition take an accused product outside the claim scope and which additions do not. See Maj. Op. 24–26.

In essence, Horizon’s petition asks whether the definiteness requirement of § 112 applies to claims that use the transitional phrase “consisting essentially of,” just as it applies to every other kind of claim. The en banc court does not need to answer that question; it answers itself. Horizon’s petition should be denied.

I. The majority correctly held that § 112’s definiteness requirement applies to the claim term “consisting essentially of.”

Section 112 of the Patent Act requires that a patent specification “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112 ¶ 2 (pre-AIA).¹ “The patent laws have retained this requirement of definiteness” since the enactment of the first Patent Act in 1790. *Nautilus*, 572 U.S. at 901–02. And, as the Supreme Court has recognized in an unbroken line of authority extending

¹ The post-AIA version of the statute contains identical language. See 35 U.S.C. § 112(b) (AIA).

back at least 150 years, the definiteness requirement serves a critical purpose: it ensures that the patent “inform[s] the public . . . of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.” *Permutit*, 284 U.S. at 60 (citing *Merrill v. Yeomans*, 94 U.S. 568, 573 (1876)); accord Maj. Op. 25–26. “[A] patent must be precise enough to provide clear notice of what is claimed, thereby ‘apprising the public of what is still open to them.’” *Nautilus*, 572 U.S. at 909 (alterations omitted) (quoting *Markman v. Westview Instruments*, 517 U.S. 370, 373 (1996)).

Under the Supreme Court’s decision in *Nautilus*, § 112 requires that “a patent’s claims, viewed in light of the specification and the prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” 572 U.S. at 910. “The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable.” *Id.*

Section 112’s definiteness requirement applies to all claims and all claim terms. It brooks no exception for the phrase “consisting essentially of.” If that self-evident proposition needed confirmation, this Court provided it in *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351 (Fed. Cir. 1998). *PPG Industries* acknowledged that “consisting essentially of” claims are sometimes “not as precise or specific as [they] might be,” but explained that the resulting imprecision is

“permissible” “[a]s long as the result complies with the statutory requirement to ‘particularly point out and distinctly claim the subject matter which the applicant regards as his invention.’” *Id.* at 1355 (alterations omitted) (quoting 35 U.S.C. § 112 ¶ 2); *contra* Horizon Pet. 10–11 (wrongly suggesting that this Court has never stated that “consisting essentially of” terms must comply with § 112).

Horizon does not and cannot cite any authority suggesting that § 112’s definiteness requirement does not apply to the term “consisting essentially of.” Instead, Horizon argues (at 1) that the basic and novel properties of an invention claimed using the “consisting essentially of” transitional phrase need not themselves be definite because “the ‘basic and novel properties’ of the invention are not claim limitations.”

This argument is flatly inconsistent with *Nautilus*. *Nautilus* made clear that claims must define “the scope of the invention with reasonable certainty.” 572 U.S. at 910. Even though an invention’s basic and novel properties are not necessarily recited in “consisting essentially of” claims, those properties still define the *scope of the invention*: they tell potential infringers which additions to the claimed composition take a potentially infringing product outside the scope of the claims and which do not. *See* Maj. Op. 24 (“By using the phrase ‘consisting essentially of’ in the claims, the inventor . . . incorporate[s] into the scope of the claims an evaluation of the basic and novel properties.”). And, as the majority correctly held,

because the basic and novel properties are part of the scope of the invention, they are necessarily subject to the definiteness requirement. Maj. Op. 26.

Horizon states (at 1) that “a product need not satisfy the ‘basic and novel properties’ of the invention to infringe.” Elsewhere, Horizon notes (at 13–14) that “any composition that does not include each of the recited ingredients will fall outside of” the bounds of a “consisting essentially of” claim. These statements are true, but they do not support Horizon’s argument. And they do not address the fundamental question of how to assess infringement of a composition that contains the claimed ingredients in addition to other non-claimed ingredients. Suppose Patentee patents a composition “consisting essentially of” ingredients 1, 2, and 3. Competitor wishes to make a competing composition that contains ingredients 1, 2, and 3, but Competitor also wants to avoid infringing Patentee’s patent. If Competitor adds to its composition ingredient 4, and ingredient 4 materially affects one of the basic and novel properties of the invention, Competitor’s product no longer infringes. But, if the basic and novel properties of the invention are indefinite—thus making it impossible for Competitor to know whether those properties have been materially affected—then Competitor will not know whether the addition of ingredient 4 will result in an infringing product or not. The resulting “zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims” is precisely the outcome that the definiteness

requirement is supposed to prevent. *Nautilus*, 572 U.S. at 909–10, 912 (quoting *United Carbon*, 317 U.S. at 236); *accord* Maj. Op. 24.²

To be sure, Horizon might have attempted to obtain a broader claim, so that it would be irrelevant whether an infringer’s extra ingredients changed any basic and novel properties of the invention. Horizon might have used the phrase “comprising” instead of “consisting essentially of.” But Horizon did not do so because it *could* not. During prosecution, Horizon’s original claims used the phrase “comprising,” but, due to prior art rejections, it was forced to narrow its claims. *See* Appx2430. And, in order to gain allowance, Horizon argued that certain prior art ingredients did not affect the basic and novel properties of its invention. *See id.* In other words, the only reason that Horizon has these patents is because it relied on the supposed basic and novel properties of its invention.

Horizon also might have attempted to obtain a narrower claim by using “consisting of,” a closed transitional phrase that would raise no indefiniteness concerns. But Horizon did not do that either, presumably because such a claim

² Horizon states in passing (at 6) that “[n]o evidence concerning the impact of an unrecited ingredient on drying time or stability was presented by Actavis before the District Court.” The dissent made a similar observation. *See* Dissenting Op. 5. But that is irrelevant. Indefiniteness is an inquiry that is independent from—and logically prior to—the infringement inquiry. Claims that are indefinite “by definition[] cannot be construed. Without a discernable claim construction, an infringement analysis cannot be performed.” *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1342 (Fed. Cir. 2003).

would exclude from infringement any compositions with any ingredients other than those recited in the claim. Horizon wants to eat its cake and have it too: it wants to use the phrase “consisting essentially of” to both narrow the claim to avoid prior art *and* keep the claim broad and ambiguous enough so that competitors cannot know how to escape infringement. Section 112 specifically prevents this perverse result.

In short, the definiteness requirement of § 112 applies to “consisting essentially of” claims. And, because the basic and novel properties of an invention define the scope of such claims, the definiteness requirement applies to those properties, just as it does every other aspect of the claims. Horizon’s contrary position is unsupported, illogical, and inconsistent with binding Supreme Court precedent. The majority correctly rejected it.

II. Horizon’s criticisms of the majority’s analysis are unfounded.

Horizon presents a grab-bag of critiques of the majority’s analysis. None has any merit.

A. The majority’s holding is faithful to established precedent.

Horizon first contends (at 7) “that the panel majority’s treatment of ‘consisting essentially of’ is ‘contrary to long-standing law and practice’” (quoting Dissenting Op. 5). But it is Horizon’s argument, not the majority’s holding, that conflicts with settled precedent.

Horizon’s argument appears to be that, because the phrase “consisting essentially of” is “a term of art with a definite legal definition,” Horizon Pet. 7, it can *never* be indefinite. But Horizon’s conclusion does not follow from its premise. As noted above, everyone agrees that “consisting essentially of” has an established legal definition: it permits inclusion of the ingredients listed in the claim, as well as other ingredients that do not affect the basic and novel properties of the invention. But, as the majority explained, that does not resolve the definiteness inquiry:

The definiteness inquiry focuses on whether a POSITA is reasonably certain about the scope of the invention. . . . [I]f a POSITA cannot ascertain the bounds of the basic and novel properties of the invention, then there is no basis upon which to ground the analysis of whether an unlisted ingredient has a material effect on the basic and novel properties.

Maj. Op. 28.³ In other words, unless the basic and novel properties can be accurately measured—that is, unless they are definite—the scope of a “consisting

³ In a similar way, a claim term can be indefinite even if the specification defines the term explicitly if the definition itself renders the scope of the invention uncertain. That is because, “even if a claim term’s definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.” *Bombardier Recreational Prods. Inc. v. Arctic Cat Inc.*, 785 F. App’x 858, 867 (Fed. Cir. 2019) (quoting *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008)). For example, in *Bombardier*, this Court affirmed a finding that the claim term “seat position defined by the seat” was indefinite—even though the term was undisputedly defined in the specification—because the resulting claim scope was impermissibly uncertain. *See id.*

essentially of’ claim will be impermissibly uncertain. As explained *supra* Section I, this conclusion follows inexorably from *Nautilus*. Horizon’s contrary position is thus foreclosed by binding precedent.

Horizon next sets up and knocks down a straw man, stating (at 10) that this Court has “never [] held that the phrase ‘consisting essentially of’ is invalid under 35 U.S.C. § 112 ¶ 2 because of its inherent imprecision.” The majority, however, explicitly stated that “the phrase ‘consisting essentially of’ is not per se indefinite.” Maj. Op. 24. It is indefinite *only* where, as here, the bounds of the basic and novel properties of the invention are not ascertainable with reasonable certainty. *See id.* at 24–25. Horizon’s suggestion that the majority applied a per se rule of indefiniteness is thus flatly incorrect.

Finally, Horizon notes (at 10–11) that this case represents the first time that this Court has analyzed the definiteness of an invention’s basic and novel properties. That is true, but it does not make the majority’s decision “a stark departure from [] long-established precedent,” Horizon Pet. 11. (On Horizon’s logic, a court could never answer a question of first impression without effecting a “stark departure” from precedent.) Indeed, had the majority held that basic and novel properties need *not* be definite—even though they define the scope of the claims—*that* would have been a stark departure from over a hundred years of

Supreme Court precedent holding that patents must “clearly circumscribe what is foreclosed from future enterprise.” *United Carbon*, 317 U.S. at 236.

B. The majority correctly held that the definiteness of an invention’s basic and novel properties is a legal question of claim construction.

Horizon also argues (at 9–10), citing *PPG Industries*, that “the application of ‘basic and novel properties’ is a factual question,” rather than an issue of claim construction. What *PPG Industries* actually says, however, is that “the task of determining whether the construed claim reads on the accused product is for the finder of fact.” 156 F.3d at 1355. In the context of a “consisting essentially of” claim, that means that 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. *See, e.g., Trs. of Bos. Univ. v. Everlight Elecs. Co.*, 23 F. Supp. 3d 50, 65 (D. Mass. 2014). But that is a separate inquiry from the issue here: whether a skilled artisan can discern with reasonable certainty when a basic and novel property has been materially affected. *See* Maj. Op. 25–26. The latter question is “an issue of claim construction and a question of law.” *Cordis Corp. v. Bos. Sci. Corp.*, 561 F.3d 1319, 1331 (Fed. Cir. 2009). Thus, “courts evaluating claims that use the phrase ‘consisting essentially of’ may ascertain the basic and novel properties of the invention at the claim construction stage,” and if a skilled artisan could not “ascertain the bounds of

th[ose] properties,” the court must hold the claim indefinite as a matter of law.

Maj. Op. 28; *see also AK Steel*, 344 F.3d at 1239–40 (determining the basic and novel properties as a matter of claim construction by consulting the specification).⁴

C. The majority correctly held that § 112 requires the scope of the invention—not just the words in the claim—to be discernable with reasonable certainty.

Horizon next contends (at 11–13) that the basic and novel properties of an invention are not subject to the definiteness requirement of § 112 because those properties are not recited in the claims. This argument is wide of the mark. As the majority explained, “[b]y using the phrase ‘consisting essentially of’ in the claims,” an inventor “incorporate[s] into the scope of the claims an evaluation of the basic and novel properties.” Maj. Op. 24. That is because “[t]he use of ‘consisting essentially of’ implicates not only the items listed after the phrase, but also those . . . ingredients . . . that do not materially affect the basic and novel properties of the invention.” *Id.* In other words, the basic and novel properties are part of the scope of the invention. And—as *Nautilus* held—the patent must “inform those skilled in the art about the *scope of the invention* with reasonable certainty.” 572 U.S. at 910 (emphasis added).

⁴ Horizon admitted, both in its opening appeal brief and in the district court, that courts may properly identify the basic and novel properties of the invention as part of claim construction. *See* Horizon Opening Br. 33; Appx3944 n.2.

Horizon accuses (at 12) the majority of “import[ing]” the basic and novel properties “from the specification into the claim.” This charge is ironic. It was Horizon—the patentee—who imported the basic and novel properties into the claim, through its use of the phrase “consisting essentially of” during prosecution. Horizon made a conscious choice to use that “partially open” transitional phrase rather than the more restrictive “close-ended” transitional phrase “consisting of.” Maj. Op. 22, 33 n.8. Horizon must now live with the consequences of that choice.

Echoing a statement made by the dissent, Horizon asserts (at 13) that “it is ‘hard to imagine a clearer statement than a list of the ingredients that the claimed formulation “consists essentially of”” (quoting Dissenting Op. 5). As the majority aptly responded,

[i]t is not. A clearer statement would be a list of ingredients that the claimed formulation “*consists of*,” which, as we previously noted, is a ‘closed claim’ confined to the listed ingredients or steps in a claim.

Maj. Op. 33 n.8. Again, Horizon might have used “consists of,” but, in an attempt to obtain broader patent coverage, it did not. It now must live with its decision.

D. The definiteness requirement is not new, and it does not create any uncertainty.

Horizon closes (at 15) its petition with the dramatic claim that “the panel majority’s decision creates a ‘new rule of claiming compositions’ which ‘casts countless patents into uncertainty” (quoting Dissenting Op. 10). This straw man is easily dismissed.

The requirement that patents provide the public with fair notice about the bounds of their inventions is far from new. As the *Nautilus* Court noted, the very first Patent Act (enacted in 1790) required that patents contain a description of their invention that “‘shall be so particular’ as to ‘distinguish the invention or discovery from other things before known and used.’” 572 U.S. at 902 (quoting Act of Apr. 10, 1790, § 2, 1 Stat. 110). And the definiteness requirement set forth in § 112 today has been in the statute—substantively unaltered—since 1870. *See id.* The majority’s holding here is simply an application of this bedrock principle of patent law to a specific set of facts.

Horizon also suggests (at 15–16) that patentees who draft “consisting essentially of” claims will now have “to design and describe in the patent specification how to measure each of the infinite potential unrecited ingredients that could be added and set forth precisely the metes and bounds of what effect is considered material.” Not so. The majority explicitly noted that it was not “requiring that the patent owner draft claims to an untenable level of specificity.” Maj. Op. 33. All that is required is that the basic and novel properties of the invention are “sufficiently definite in scope . . . to afford clear notice of the claim’s bound.” *Id.* at 34 n.8. Here, the “better drying time” property of the invention at issue here did not satisfy that requirement, because the patent set forth two different ways of evaluating drying time that yielded inconsistent results. *See id.* at

32–33. In other words, the patents here did not even provide an objective and consistent way to *measure* drying time, much less suggest what magnitude of effect on drying time would be considered “material.” The majority’s holding that “the phrase ‘consisting essentially of’ was indefinite” “on these particular facts,” Maj. Op. 33, is hardly likely to spawn the parade of horrors set forth in Horizon’s petition.

Finally, Horizon asserts (at 17) that, “[m]oving forward, in every instance, courts will have to identify the ‘basic and novel properties’ and determine whether they have ‘objective boundaries.’” It is certainly true that, if a patentee asserts a claim using the phrase “consisting essentially of,” and if the accused infringer argues in response that the phrase “consisting essentially of” is indefinite, the court will have to address the argument. But, while Horizon may believe that the application of § 112’s definiteness requirement is a “burden,” Horizon Pet. 17, Congress determined that this burden is outweighed by the benefit that results when the public has fair notice of the scope of patented inventions. *See* 35 U.S.C. § 112; 28 U.S.C. § 1338.

* * *

The Court should deny Horizon’s petition for rehearing en banc.

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