

No. 20-88

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**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  
United States Court of Appeals for the  
Federal Circuit**

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**BRIEF IN OPPOSITION**

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### QUESTION PRESENTED

Section 112 of the Patent Act requires patents to conclude with claims that “particularly point[] out and distinctly claim[] the subject matter” of the invention. A patent is invalid for indefiniteness under § 112 if the claims “fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

The claims here recite a topical gel “consisting essentially of” certain ingredients, meaning the claims cover compositions that contain (i) the listed ingredients and (ii) other ingredients that do not materially affect the “basic and novel properties” of the invention. *See In re Herz*, 537 F.2d 549, 551–52 (C.C.P.A. 1976). One of the gel’s basic and novel properties is “better drying time” relative to prior liquid formulations. The courts below concluded—in findings Horizon no longer challenges—that persons skilled in the art could not discern with reasonable certainty whether additional ingredients would materially affect the gel’s drying time because the patent provides two methods of measuring “drying time” that yield inconsistent results and does not specify which method to use.

The question presented is:

Whether the courts below erred in finding the claims indefinite, where unchallenged findings establish that a skilled artisan could not discern with reasonable certainty what additional ingredients would materially affect the invention’s basic and novel properties and thus could not determine the scope of the invention.

**RULE 29.6 STATEMENT**

Actavis Laboratories UT, Inc. is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., which is publicly traded. Teva Pharmaceutical Industries Ltd. is the only publicly-traded company that owns 10% or more of Actavis Laboratories UT, Inc.

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## INTRODUCTION

The court of appeals correctly held Petitioner Horizon’s patent claims indefinite by applying well-established legal principles to a particular—and particularly idiosyncratic—set of facts. Horizon offers no reason why that fact-bound decision warrants this Court’s review. On the contrary, the court of appeals’ decision followed directly from the language of the Patent Act and this Court’s precedent. There is no split of authority. And, despite Horizon’s contention (at 3), the decision below creates no “confusion” regarding the validity of patents employing the phrase “consisting essentially of.” Instead, it is Horizon’s approach that, if accepted, would “overturn[] decades of jurisprudence” and introduce conflict and confusion into the law.

Everyone in this case agrees that a patent claim’s use of the phrase “consisting essentially of” means that the claim covers compositions that contain (i) the listed ingredients and (ii) any other ingredients, so long as those other ingredients do not materially affect the “basic and novel properties” of the invention. *See* Pet. 6–7 (citing *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003)). Horizon’s claims recite a topical pharmaceutical gel “consisting essentially of” various ingredients, and the patent specification identifies “better drying time” (relative to an earlier liquid formulation) as one of the invention’s basic and novel properties. The courts below concluded—in a finding no longer challenged by Horizon—that a skilled artisan would not know how to tell with reasonable certainty whether an additional ingredient would materially affect the gel’s

“drying time” 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. Pet. App. 33.

From this finding, it inexorably follows that Horizon’s “consisting essentially of” claims 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—and therefore remove a competing formulation from the scope of the claims—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).

Yet Horizon takes (at 10) the incredible position that the claim term “consisting essentially of” can *never* be indefinite because it is “a term of art with a *definite* legal definition.” 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 courts below correctly found that the claims here do not meet that standard.



Horizon contends (at 2–3) 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 invention with reasonable certainty”). The answer is yes, as the court of appeals recognized. “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.” Pet. App. 24. And, “[h]aving used the phrase ‘consisting essentially of,’ and thereby incorporated unlisted ingredients or steps that do not materially affect the basic and novel properties of the invention, a drafter cannot later escape the definiteness requirement by arguing that the basic and novel properties of the invention are in the specification, not the claims.” *Id.*

In essence, Horizon asks whether the definiteness requirement of § 112 applies to patent claims that use the transitional phrase “consisting essentially of”—just as it applies to every other kind of claim—or whether such claims need not comply with the statute. This Court does not need to answer that question; it answers itself. The petition for certiorari should be denied.

## STATEMENT OF THE CASE

### A. Factual background

1. The patents at issue in this case claim topical gels that are used to treat osteoarthritis. See Pet.

App. 3–4. Horizon sued Respondent Actavis for infringement of these and other patents when Actavis sought to market a generic version of Horizon’s PENNSAID 2% product, a topical anti-inflammatory indicated to treat osteoarthritis of the knee. *Id.* at 5.

The relevant claims recite a topical formulation “consisting essentially of” certain ingredients, including diclofenac sodium, dimethyl sulfoxide, ethanol, propylene glycol, hydroxypropyl cellulose, and water. *Id.* at 4. As all parties agree, “the phrase ‘consisting essentially of,’ when used in a formulation patent, reflects that the recited formulation includes (a) the listed ingredients that follow the phrase, and (b) unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *Id.* at 6 (citations omitted). Horizon argued, and the courts below agreed, that the “basic and novel properties” of the invention here include “better drying time” relative to a prior-art liquid formulation and “favorable stability,” among others. Pet. 7 (citing Pet. App. 23).

2. “Consisting essentially of” is one of three so-called “transitional phrases” that patentees may use to define the scope of claims to compositions (or methods) that include specified ingredients (or steps). *See Conoco, Inc. v. Energy & Env’tl. Int’l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). The phrase “consisting of” is the narrowest of the three: a claim to a composition “consisting of” certain ingredients covers only compositions with those ingredients and no others. *See id.* The phrase “comprising” is the broadest: a “comprising” claim is “fully open” and therefore covers any composition that contains the

listed ingredients, regardless of whether it also contains other ingredients. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). “A ‘consisting essentially of’ claim occupies a middle ground” because it permits some other ingredients, but only those that do not affect the invention’s basic and novel properties. *Id.*

The choice of transitional phrase represents a trade-off for patentees. It is easier to show infringement of “comprising” claims, since such claims render it irrelevant whether the potential infringer’s product contains any unlisted ingredients. However, the breadth of these claims makes it harder to defend their validity, since any prior-art composition containing the listed ingredients (regardless of whether the composition contains any other ingredients) is potentially invalidating.

This very case illustrates that trade-off. Horizon’s application that led to the patents at issue originally sought claims that used the broadest transitional phrase, “comprising.” But, due to prior-art rejections during patent prosecution before the U.S. Patent and Trademark Office, Horizon was forced to narrow its claims to the “consisting essentially of” format to avoid the prior art. *See* C.A.J.A. 2430. Specifically, in order to gain allowance of its patents, Horizon argued that certain prior-art ingredients would have affected the basic and novel properties of its invention. *See id.*

Horizon might have obtained an even narrower claim by using “consisting of,” which would have indisputably overcome the prior art identified by the Patent Office. But Horizon did not do that,

presumably because of the ease with which a competitor could add an additional ingredient and so avoid infringement of such a claim.

### **B. Proceedings in the district court**

In the district court, Actavis argued that Horizon's "consisting essentially of" claims were invalid as indefinite under 35 U.S.C. § 112. The district court agreed. The court concluded that "better drying time" and "favorable stability" were both indefinite and, accordingly, that the claims as a whole were indefinite because one skilled in the art "would lack 'reasonable certainty' about whether an additional ingredient would materially alter the basic and novel properties of the claimed invention." Pet. App. 84.

1. **Better drying time.** The district court explained that the "better drying time" property was indefinite because "the specification described two different methods for evaluating 'better drying time'" and the two methods "did not provide consistent results at consistent times." Pet. App. 6. Specifically, the two tests measure drying time in inconsistent ways (subjectively and objectively), and the patent specification contradicts itself in reporting on the results of the objective test.

In the first test, equal amounts of the claimed gel and a prior-art liquid formulation were "tested on opposite limbs," and the dryness of the patient's skin was subjectively assessed after 30 minutes. C.A.J.A. 139 (10:16–21). According to the specification, "[w]ithin thirty (30) minutes the compositions of the invention are almost completely dry whereas a

significant amount of the [prior-art] liquid formulation remains.” *Id.*

The second test quantitatively “measured the residual weight of formulations [placed] in weighing dishes.” *Id.* (10:22–27). Table 12 of the patent displays the data from this test:

TABLE 12

Drying times				
Drying times for gels and a comparative liquid formulation solution. Equal weights of each formulation were measured and spread on weigh dishes. The weight of each remaining formulation was then followed with time. The gels of this invention showed faster drying kinetics than the comparative liquid formulation, with F14/2 showing the fastest drying rate. These gels also had improved “spreadability” characteristics, which most likely contributed to this improvement in drying rates.				
Formulation name				
Percentages in	Comparative wt/wt %	F14/2 gel 2.5% wt/wt %	F14/2 gel 4.0% wt/wt %	F971 wt/wt %
Water	18.81	12.5	12.5	17.16
Dimethyl Sulfoxide	45.5	45.5	45.5	45.5

TABLE 12-continued

Drying times				
Drying times for gels and a comparative liquid formulation solution. Equal weights of each formulation were measured and spread on weigh dishes. The weight of each remaining formulation was then followed with time. The gels of this invention showed faster drying kinetics than the comparative liquid formulation, with F14/2 showing the fastest drying rate. These gels also had improved "spreadability" characteristics, which most likely contributed to this improvement in drying rates.				
Propylene glycol	11.2	11	11	11.2
Ethanol	11.79	26.5	25	11.79
Glycerine	11.2			11.2
Diclofenac Sodium	1.5	2	2	2
Thickener	none	HY119	HY119	Carbopol 971
wt/wt % thickener		2.5	4	1:15
% Remaining				
Time (hr)	Comparative	F14/2 gel 2.5%	F14/2 gel 4.0%	F971
0.000	100	100	100	100
0.083	98.1	93	92.6	100.3
0.167	96.7	92.9	91.8	100.3
0.333	95.7	92.7	93	100.2
0.500	95.6	92.7	93.3	100
0.750	95.5	92.1	92.3	99.8
1.000	95.9	92	91.8	99.7
4.000	93	71	70.7	86.8
24.000	88.7	32.4	23.5	58.8

C.A.J.A. 145–146. Although the specification contends that “the three gel formulations displayed more rapid drying than the liquid formulation,” C.A.J.A. 145 (21:62–22:1), this statement—as the district court observed—“is simply not supported by the data.” Pet. App. 83. The F971 gel had a greater percentage weight remaining relative to the liquid formulation at all measured time points up to four hours. *See* C.A.J.A. 145 (21:62–22:1); Pet. App. 83.

“In short,” the district court concluded, “the specification describes two different methods for

evaluating ‘better drying time,’ and the two methods do not provide consistent results at consistent times.” Pet. App. 83. “Further, the claimed results are not seen across all formulations of the claimed invention, and when ‘dryness’ is evaluated at any time shorter than four hours, not all formulations of the claimed invention actually exhibit ‘better drying time.’” *Id.*

**2. Favorable stability.** The district court also concluded that the “favorable stability” property was indefinite because a skilled artisan would not have known how to measure stability. Specifically, the specification linked “stability” to the degradation of the formulation into “impurity A”—a term that the district court also found to be indefinite. Pet. App. 7–8, 93.

### C. Proceedings in the court of appeals

The court of appeals affirmed the district court’s indefiniteness holding. In doing so, the panel rejected Horizon’s contention that “the *Nautilus* definiteness standard focuses on the claims and therefore does not apply to the basic and novel properties of the invention.” Pet. App. 24. This argument, the panel explained, was “misguided” because, “[b]y using the phrase ‘consisting essentially of’ in the claims, the inventor in this case incorporated into the scope of the claims an evaluation of the basic and novel properties.” *Id.* Accordingly, “it follows that those basic and novel properties . . . must provide objective boundaries for those of skill in the art.” *Id.* at 26 (citation omitted). While the basic and novel properties need not necessarily be “precise,” they must “inform, with reasonable certainty, a [skilled

artisan] of their scope within the context of the invention.” *Id.* (citing *Nautilus*, 572 U.S. at 901). Otherwise, potential infringers have “no basis upon which to ground the analysis of whether an unlisted ingredient has a material effect on the basic and novel properties.” *Id.* at 28.

The panel also agreed with the district court’s conclusion that “better drying time” was indefinite because “the two different methods for evaluating ‘better drying time’ do not provide consistent results at consistent times.” *Id.* at 30–32. In view of that conclusion, the panel did not reach the definiteness of “favorable stability.”

Judge Newman dissented. She would have held that the term “consisting essentially of” in Horizon’s patents was equivalent to the term “consisting of,” which she asserted raised no indefiniteness concerns. *See id.* at 52–53.

The full Federal Circuit denied Horizon’s petition for rehearing en banc by an 8–4 vote. Judge Lourie, joined by Judges Newman, O’Malley, and Stoll, dissented from the denial of rehearing. Judge Lourie argued that the panel majority’s holding was error because “better drying time is not in the claim, and it is the claims that the statute requires to be definite.” *Id.* at 98. In his view, the “[a]dvantages of an invention” are not subject to § 112’s definiteness requirement, even when a patentee incorporates those advantages into the scope of the claims through use of the term “consisting essentially of.” *Id.* at 99–100.

The present petition for certiorari followed.



### REASONS FOR DENYING THE PETITION

Horizon no longer contests the court of appeals' conclusion that at least one of the "basic and novel properties" of the claimed invention—"better drying time"—is indefinite. Once that conclusion is accepted, it necessarily follows that the "consisting essentially of" claims are indefinite. The basic and novel properties define the scope of a "consisting essentially of" claim, because such a claim covers additional elements *only* if those elements do not materially affect the invention's basic and novel properties. If a skilled artisan cannot discern whether the invention's basic and novel properties have been affected by the addition of such an element, the skilled artisan cannot discern the scope of the claim. That means the claim is indefinite, as the court of appeals held. That conclusion was plainly correct; there is no contrary authority; and the court's application of this well-settled law creates no confusion.

Horizon urges this Court to adopt a sweeping rule that the term "consisting essentially of" can *never* be indefinite because it is a term of art with a legal definition. Pet. 10. Horizon's proposed rule is inconsistent with decades of precedent and makes no sense as a matter of logic. The court of appeals correctly rejected it, and that decision does not warrant this Court's review.

- I. **The court of appeals’ holding follows directly from governing precedent.**
  - A. **Section 112’s definiteness requirement applies to “consisting essentially of” claims and therefore applies to the basic and novel properties of such a claim.**

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 (2010).<sup>1</sup> “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 this Court has recognized in an unbroken line of authority extending 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)). “[A] patent must be precise enough to afford 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)).

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<sup>1</sup> The pre-America Invents Act statute applies to the patents at issue by virtue of their priority date. The post-AIA version of § 112 contains identical language. *See* 35 U.S.C. § 112(b) (AIA).

Under *Nautilus*, § 112 requires that “a patent’s claims, viewed in light of the specification and 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 this self-evident proposition needed any confirmation, the Federal Circuit provided it in *PPG Industries*. There, the Federal Circuit 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.’” 156 F.3d at 1355 (alterations omitted) (quoting 35 U.S.C. § 112 ¶ 2).

Given that “consisting essentially of” claims must satisfy § 112, it necessarily follows that the basic and novel properties of the invention that are incorporated in such a claim must also satisfy § 112. This result follows directly from *Nautilus* itself. As noted above, *Nautilus* made clear that claims must define “the scope of the invention with reasonable certainty.” 572 U.S. at 910. In a “consisting essentially of” claim, the basic and novel properties themselves 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 claim and which do not. *See* Pet. App. 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, because the basic and novel properties define the scope of the invention, they are necessarily subject to the definiteness requirement.

A hypothetical illustrates the point. 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—an undisputed proposition in this case—then Competitor will not know whether the addition of ingredient 4 will materially affect those properties and thus result in a non-infringing product. 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* Pet. App. 24.

Horizon’s own argument reinforces this point. Horizon states (at 16) that a “consisting essentially of” claim places members of the public “on notice that

they can avoid infringement so long as they omit one of the required ingredients or include an additional ingredient that materially affects at least one of the five properties.” But, if the public cannot determine whether one of the basic and novel properties has been materially affected, the public cannot know whether it has avoided infringement or not. The patent laws do not permit this result. *See United Carbon*, 317 U.S. at 236 (claims must “clearly circumscribe what is foreclosed from future enterprise”).

**B. Horizon’s contrary arguments lack merit.**

1. 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 asserts (at 10) that the majority’s application of § 112 to these claims “vitiates seventy years of established usage” because “consisting essentially of” is a “term of art with a *definite* legal definition.” In other words, in Horizon’s view, “consisting essentially of” can *never* be indefinite because it has a definition.

This argument proves too much. It is true 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 court of appeals explained, that does not resolve the definiteness inquiry:

The definiteness inquiry focuses on whether a [skilled artisan] is reasonably certain about

the scope of the invention. . . . [I]f a [skilled artisan] 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.

Pet. App. 28.<sup>2</sup> In other words, unless the basic and novel properties can be accurately measured—that is, unless they are definite—the scope of a “consisting essentially of” claim will be impermissibly uncertain.

Echoing an argument made in Judge Newman’s dissent, Horizon asserts (at 15–16) that “it is ‘hard to imagine a clearer statement than a list of the ingredients that the claimed formulation “consists essentially of”” (quoting Pet. App. 48). But, as the majority aptly responded,

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<sup>2</sup> In a similar way, a claim term can be indefinite even if the specification explicitly defines the term—namely, when the explicit 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*, the Federal Circuit 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.*

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

Pet. App. 33 n.8.

2. Horizon also contends (at 13–14), echoing an argument made in Judge Lourie’s dissent, that the basic and novel properties of an invention are not subject to § 112 because the basic and novel properties are “not in the claims.” *See also* Pet. App. 99. This argument ignores that the definiteness requirement concerns the *scope of the invention* and that—by drafting claims using the transitional phrase “consisting essentially of”—the patentee necessarily defines the scope of the invention by reference to its basic and novel properties. Having made that choice, the patentee cannot thereafter “escape the definiteness requirement by arguing that the basic and novel properties of the invention are in the specification, not the claims.” *Id.* at 24.<sup>3</sup>

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<sup>3</sup> Judge Lourie’s dissent notes that “aspects of the utility or its measurement are not relevant to indefiniteness of the claims.” Pet. App. 101. As a general matter, that is true. But, by using the phrase “consisting essentially of,” the patentee defines the claim scope by reference to the invention’s basic and novel properties, which means those properties *are* highly relevant to the definiteness of the claims. And Judge Lourie’s further suggestion that the court of appeals’ holding could somehow be applied *outside* the context of “consisting essentially of” claims to impose a general requirement that patentees recite the utility of their invention in the claims, *see id.*, is simply unfounded.

This case presents a prime illustration of this point. As explained above, *see supra* Statement of the Case, Horizon attempted to obtain a broader claim by using the transitional claim term “comprising”—which would have covered any competing composition that contained the listed ingredients, regardless of whether it contained any other ingredients—but was forced by the Patent Office to narrow its claims. C.A.J.A. 2430. And Horizon gained allowance of the claims only by arguing that certain prior-art ingredients would have affected 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 the invention.

Horizon, in short, 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 result.

**C. Because Horizon no longer disputes that at least one of the invention’s basic and novel properties is indefinite, the “consisting essentially of” claims are necessarily indefinite as well.**

Once it is established that Horizon’s “consisting essentially of” claims are subject to the definiteness requirements of § 112, it necessarily follows that the court of appeals correctly found them invalid. Horizon no longer disputes the court of appeals’ conclusion that the “better drying time” property is indefinite,



nor does it dispute the district court's conclusion that the "favorable stability" property is indefinite. Because a skilled artisan could not determine with reasonable certainty whether either of those basic and novel properties has been affected and hence whether a given additional ingredient would remove a competing composition from the scope of the claim, the claim does not satisfy § 112. *See Nautilus*, 572 U.S. at 910.

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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 to every other aspect of the claims. Horizon's contrary position is unsupported, illogical, and inconsistent with this Court's binding precedent. The court of appeals correctly rejected it.

## **II. There is no conflict of authority.**

As explained above, the court of appeals' holding follows directly from well-established precedent of this Court and the Federal Circuit. Horizon identifies no case from *any* court suggesting that the term "consisting essentially of" is *per se* definite or that the basic and novel properties of an invention defined by a "consisting essentially of" claim need not satisfy § 112. There is thus no decisional conflict that would warrant this Court's intervention.

Horizon's attempts to manufacture a split of authority fail. The first mischaracterizes the decision below; the second mischaracterizes precedent.

*First*, Horizon states (at 13) that this case represents the first time the Federal Circuit has “held that the phrase ‘consisting essentially of’ is invalid under 35 U.S.C. § 112 ¶ 2 because of its inherent imprecision.” That is emphatically *not* what the court of appeals held. The court explicitly stated that “the phrase ‘consisting essentially of’ is not per se indefinite.” Pet. App. 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 court of appeals applied a *per se* rule of indefiniteness is flatly incorrect.

*Second*, Horizon contends (at 15) that, in *PPG Industries*, the Federal Circuit “held that any uncertainty associated with the phrase ‘consisting essentially of’ can and *should* be resolved by the fact-finder by assessing whether the unrecited ingredients materially affect the ‘basic and novel properties’ of the claimed composition.” Not so. *PPG Industries* says (correctly) 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. Pet. App. 27; *see also, e.g., Trs. of Bos. Univ. v. Everlight Elecs. Co.*, 23 F. Supp. 3d 50, 65 (D. Mass. 2014). But the antecedent question whether it is even possible for a skilled artisan to discern if a basic and novel property has been materially affected in the first place—that is,

whether the claim scope has definite boundaries—is an issue of claim construction “reserved for court decision.” *Nautilus*, 572 U.S. at 905–06 (citing *Markman*, 517 U.S. 370); *accord Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1331 (Fed. Cir. 2009). Indeed, Federal Circuit precedent explicitly holds that identification of an invention’s basic and novel properties is a legal issue of claim construction. *See AK Steel*, 344 F.3d at 1239–40; *accord* Pet. App. 28.<sup>4</sup> Horizon’s attempt to convert the legal issue of a claim’s compliance with § 112 into a factual question of infringement thus contravenes settled law.

### **III. The court of appeals’ faithful application of well-established law creates no uncertainty.**

Horizon closes (at 16) with the dramatic assertion that the court of appeals created a “new rule” that

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<sup>4</sup> Horizon has consistently admitted throughout this proceeding that courts may properly identify the basic and novel properties as a matter of law at the claim-construction stage. Pet. 12; Horizon Op. Br. 33; C.A.J.A. 3944 n.2. Thus, Horizon’s suggestion (at 13) that the court of appeals was applying a “new standard” by identifying the basic and novel properties as part of claim construction is, by Horizon’s own admission, incorrect.

To the extent Horizon means to now argue that terms appearing outside the claims are categorically irrelevant to claim construction (and thus to indefiniteness), Horizon’s argument is contradicted not only by *AK Steel*, but also by the Federal Circuit’s “derivative claim construction” cases. Those precedents recognize that courts may sometimes need to construe “non-claim term[s]” if “the correct construction of a claim term necessitates a derivative construction of a non-claim term.” *Advanced Fiber Techs. (AFT) Trust v. J&L Fiber Servs., Inc.*, 674 F.3d 1365, 1373 (Fed. Cir. 2012).

“casts countless patents into uncertainty.” But 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.* That requirement has never created undue uncertainty before, and Horizon provides no persuasive explanation of why it would start now.

Contrary to Horizon’s suggestion (at 17), the court of appeals did *not* hold that patentees must “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.” The court of appeals explicitly noted that it was not “requiring that the patent owner draft claims to an untenable level of specificity.” Pet. App. 33. All that is required is that the basic and novel properties be “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 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”—and all this despite the fact that the patentee strategically relied on the basic and novel properties of the invention to obtain the patent in the first place. The majority’s holding that “the phrase ‘consisting essentially of’ was indefinite” “on these particular facts,” *id.* at 33, is hardly likely to spawn the parade of horrors set forth in the petition.

Horizon also complains (at 18–19) that the Patent Office and the courts will find it “unduly complicate[d]” to determine the definiteness of “consisting essentially of” claims. It is not clear why this is so; 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. And even if Horizon were correct that compliance with and application of § 112 is a “burden,” 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. The court of appeals correctly respected Congress’s determination here, and that decision does not warrant further review.

**CONCLUSION**

The Court should deny the petition for certiorari.

Respectfully submitted,

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