United States Court of Appeals for the Federal Circuit

HZNP MEDICINES LLC, HORIZON PHARMA USA, INC.,
Plaintiffs-Appellants

v.

ACTAVIS LABORATORIES UT, INC.,
Defendant-Cross-Appellant

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

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.

Decided: October 10, 2019

CARYN BORG-BREEN, Green, Griffith & Borg-Breen LLP, Chicago, IL, argued for all plaintiffs-appellants. Also represented by ROBERT FRITZ GREEN, JESSICA MACKAY.

MICHAEL E. JOFFRE, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, argued for defendant-cross-appellant. Also represented by JOHN CHRISTOPHER ROZENDAAL, KRISTINA CAGGIANO KELLY, WILLIAM H. MILLIKEN.

Before PROST, *Chief Judge,* NEWMAN and REYNA, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* REYNA.

Opinion concurring in part and dissenting in part filed by *Circuit Judge* NEWMAN.

REYNA, *Circuit Judge.*

HZNP Medicines LLC and Horizon Pharma USA, Inc. ("Horizon") appeal from the U.S. District Court for the District of New Jersey's judgment of invalidity and noninfringement. Actavis Laboratories UT, Inc. ("Actavis") cross-appeals the district court's judgment of nonobviousness. We affirm.

BACKGROUND

Horizon[1] is the assignee of U.S. Patent Nos. 8,217,078 ("the '078 patent"); 9,132,110 ("the '110 patent"); 8,618,164 ("the '164 patent"); 9,168,304 ("the '304 patent"); 9,168,305 ("the '305 patent"); 8,546,450 ("the '450 patent"); 9,101,591 ("the '591 patent"); 8,563,613 ("the '613 patent"); 9,220,784 ("the '784 patent"); 8,871,809 ("the '809 patent"); 8,252,838 ("the '838 patent"); and 9,066,913 ("the '913 patent") (collectively, "the patents-at-issue" or "Horizon's patents"). The patents-at-issue generally relate to methods and compositions for treating osteoarthritis and can be divided into

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[1] During the pendency of this appeal, HZNP Medicines LLC substituted itself as plaintiff-appellant for Horizon Pharma Ireland Limited and HZNP Limited, explaining that it is now the lawful holder and owner of New Drug Application No. 204623 and of U.S. Patent Nos. 8,217,078; 8,252,838; 8,546,450; 8,563,613; 9,066,913; 9,101,591; 9,132,110; 9,168,304; 9,168,305; and 9,220,784.

two groups, with the patents in each group sharing a substantially similar specification.

The first group of patents consists of method-of-use patents, including the '450, '078, '110, and '164 patents. (the "method-of-use patents"). Claim 10 of the '450 patent is illustrative of the asserted claims of the method-of-use patents:

> 10. A method for applying topical agents to a knee of a patient with pain, said method comprising:
>
> > applying a first medication consisting of a topical diclofenac preparation to an area of the knee of said patient to treat osteoarthritis of the knee of said patient, wherein the topical diclofenac preparation comprises a therapeutically effective amount of a diclofenac salt and 40–50% w/w dimethyl sulfoxide;
> >
> > waiting for the treated area to dry;
> >
> > subsequently applying a sunscreen, or an insect repellant to said treated area after said treated area is dry, wherein said step of applying a first medication does not enhance the systemic absorption of the subsequently applied sunscreen, or insect repellant; and
> >
> > wherein said subsequent application occurs during a course of treatment of said patient with said topical diclofenac preparation.

'450 patent col. 73 l. 35–col. 74 l. 11.

The second group of patents consists of formulation patents, including the '838, '591, '304, '305, '784, '613, '809, and '913 patents. (the "formulation patents"). Claim 49 of

the '838 patent is illustrative of the asserted claims of the formulation patents:

> 49. A topical formulation consisting essentially of:
>
> 1–2% w/w diclofenac sodium;
>
> 40–50% w/w DMSO;
>
> 23–29% w/w ethanol;
>
> 10–12% w/w propylene glycol;
>
> hydroxypropyl cellulose; and
>
> water to make 100% w/w, wherein the topical formulation has a viscosity of 500–5000 centipoise.

'838 patent col. 30 ll. 60–67.

Both groups of patents are listed in the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Horizon's PENNSAID® 2% product. PENNSAID® 2% is a nonsteroidal anti-inflammatory drug ("NSAID") and the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of pain of osteoarthritis of the knees.

Relevant to the development of PENNSAID® 2% is prior art PENNSAID® 1.5%. PENNSAID® 1.5% also treats osteoarthritis knee pain but differs from PENNSAID® 2% both in formulation and recommended dosage. As to dosage, PENNSAID® 1.5% directs the user to administer the formulation by applying 40 drops of PENNSAID® 1.5% on each painful knee, four times a day. J.A. 6923. PENNSAID® 2% improved upon this dosing regimen by reducing the frequency of application to a recommended dose of 40 mg of the formulation, applied through "2 pump actuations on each painful knee, 2 times a day." J.A. 6649–51.

Actavis sought to market a generic version of PENNSAID 2% and filed Abbreviated New Drug Application ("ANDA") No. 207238.[2] The ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), stating that the patents-at-issue were invalid or would not be infringed by Actavis's generic product. The filing of an ANDA with a Paragraph IV certification constitutes an act of artificial patent infringement under 35 U.S.C. § 271(e)(2)(A), which allows litigation to commence before actual sale of an accused product has occurred. *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1126 (Fed. Cir. 2018).

On December 23, 2014, after receiving notice of Actavis's Paragraph IV certification, Horizon filed suit in the District of New Jersey, alleging infringement of the patents-at-issue under § 271(e)(2)(A).

I. Claim Construction

At the district court, the parties disputed the construction of various terms in the asserted claims. Both sides filed claim construction briefs. The district court conducted *Markman* hearings on March 3, 2016, and June 7, 2016. On August 17, 2016, the district court issued its *Markman* order, finding three terms in the asserted claims of the formulation patents to be indefinite.

First, the district court found that the term "the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity" was indefinite because

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[2] Watson Laboratories, Inc., ("Watson") was the holder of the ANDA when it was filed with the FDA. Watson later changed its name to Actavis Laboratories UT, Inc. Actavis is now the holder of the ANDA. For simplicity, we refer to Watson and Actavis Laboratories, UT Inc. as Actavis.

the identity of "impurity A" is unknowable to a person of ordinary skill in the art ("POSITA").

Second, the district court found that the term "the formulation degrades by less than 1% over 6 months" was indefinite because neither the claims nor the specification disclose the means to evaluate degradation.

Third, the district court found that the term "consisting essentially of" was indefinite. In that regard, the district court began by recognizing that 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. *See* J.A. 14–15 (citing *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998)). Because the parties disputed the basic and novel properties, the district court determined that in this case identification of those properties was required. The district court therefore concluded that "[b]ecause the basic and novel properties of an invention are part of the construction of a claim containing the phrase 'consisting essentially of,' the *Nautilus* standard applies to the assessment of an invention's basic and novel properties." J.A. 22–23 (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014)).

Turning to the basic and novel properties of the invention, the district court noted that the specification identified five properties: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. The district court focused on the "better drying time" property and held that this basic and novel property was indefinite. In doing so, the district court emphasized that the specification described two different methods for evaluating "better drying time." Those two methods, however, did not provide consistent results at consistent times. Faced

with this inconsistency, the district court was persuaded by expert testimony that a POSITA would not know under which standard to evaluate the drying rate of the claimed invention. According to the district court, this prevented a POSITA from being able to have "reasonable certainty" about the scope of the basic and novel properties of the invention, thereby rendering the term "consisting essentially of" indefinite. J.A. 27.

On August 30, 2016, Horizon filed a motion for reconsideration of the claim construction. Horizon argued that the district court erred by failing to consider indefiniteness on a claim-by-claim basis. Horizon also contended that it had been prevented from fully developing the record in relation to the "better drying time" property. On January 4, 2017, the district court conducted a hearing on the motion for reconsideration, and on January 6, 2017, it issued an opinion denying Horizon's motion for reconsideration and maintaining its initial claim constructions and indefiniteness determinations.

The district court concluded that Horizon's arguments on reconsideration lacked merit. As to the claim-by-claim argument, the district court noted that Horizon chose to address the issue in relation to the formulation patents as a whole, and that this was a new argument raised for the first time in a motion for reconsideration, which is improper. The district court also found that Horizon had ample notice and opportunity to present evidence and develop the record during the two *Markman* hearings, the supplemental briefing in between those hearings, and during the ten weeks between the second hearing and the *Markman* order.

The district court bolstered its conclusion that the basic and novel properties were indefinite by analyzing the "favorable stability" property, which had not been addressed in the initial *Markman* order. Because the specification failed to provide the requisite guidance for a POSITA to

evaluate stability, the district court found that the "favorable stability" property was indefinite which in this case, by extension, rendered the phrase "consisting essentially of" indefinite.

II. Summary Judgment

On January 27, 2017, after the district court reaffirmed its claim constructions and related indefiniteness determinations, Actavis filed a motion for summary judgment of noninfringement. Actavis argued that there was no dispute that Actavis did not directly infringe the patents-at-issue, and that, while Horizon premised its allegations of induced infringement upon the labeling of Actavis's ANDA product, there was also no material factual dispute that Actavis's proposed label does not induce infringement.

In evaluating the inducement argument, the district court considered, among other things, the asserted claims of the method-of-use patents and the respective labels for both Horizon's and Actavis's products. As to the asserted claims of the method-of-use patents, the district court found that Horizon's claimed methods required the following steps: (1) application of the medication to knee, (2) waiting for the area to dry, and (3) application of sunscreen, insect repellant, or a second topical medication. To perform Horizon's claimed methods, all the steps must be conducted.

Turning to the parties' respective labels, according to the district court, both were essentially the same; the main distinction being that Actavis's proposed ANDA label replaced "PENNSAID" with "diclofenac sodium topical solution." In relevant part, the parties' labels warn to "[w]ait until the treated area is dry" before applying a second topical agent, such as sunscreen, insect repellant, or covering the area with clothing. The district court held that this warning was insufficient to show induced infringement because Horizon's claimed method *requires* application of a second topical agent whereas the label *merely permits*,

without encouraging, post-product application of sunscreen, insect repellant, or a second topical medication. The district court thus granted summary judgment in Actavis's favor, concluding that Horizon had not met its burden to show that Actavis's label induced infringement of the method-of-use patents.

III. Trial

The district court's *Markman* and summary-judgment orders disposed of most of the asserted claims of the patents-at-issue. At trial, only one claim remained—claim 12 of the '913 patent. Actavis maintained that claim 12 of the '913 patent was invalid as obvious. Actavis stipulated that if the claim was found not invalid at trial, its ANDA product would infringe the claim. The stipulation thus narrowed the trial court's focus to obviousness.

Actavis's obviousness theory was that the changes made to PENNSAID® 1.5%, which resulted in the PENNSAID® 2% formulation, would have been obvious to a POSITA based upon the prior art available at the time of the invention.

The formulation differences between PENNSAID® 1.5% and PENNSAID® 2% (as recited in claim 12 of the '913 patent)[3] are as follows:

Ingredient	Prior Art PENNSAID® 1.5%	Formulation of '913 Patent, Claim 12
Diclofenac sodium	1.5%	2%
Dimethyl sulfoxide ("DMSO")	45.5%	45.5%
Ethanol	11.79%	23-29%
Propylene glycol	11.2%	10-12%
Hydroxypropyl cellulose ("HPC")	-	2.5%
Glycerin	11.2%	Not required, but not excluded
Water	To make 100%	To make 100%

J.A. 15915 (table generated by the district court). Each of the ingredients listed above performs a specific function. Diclofenac sodium is the active ingredient. Dimethyl sulfoxide ("DMSO") is a penetration enhancer, which enhances absorption of the drug into the skin. Ethanol is both a solvent, which dissolves the active ingredient for absorption of the drug into the skin, and a penetration enhancer. Propylene glycol is a solvent. Hydroxypropyl cellulose ("HPC") is a thickening agent, which increases the viscosity of a formulation. Glycerin is a humectant, which is a non-volatile substance that holds water onto the skin. And water is a solvent.

Actavis contended that the drawbacks to PENNSAID® 1.5%—frequent application and vulnerability to run-off—

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[3] Claim 12 of the '913 patent recites a method for applying the formulation that is collectively recited in claims 1, 8, and 9.

were known, and that a POSITA would have been motivated to modify PENNSAID® 1.5% to address these drawbacks by: (a) increasing the absorption to reduce application frequency; (b) thickening the formulation; and (c) reducing the drying time to prevent run-off. Actavis proposed that a POSITA would have had a reasonable expectation that these modifications would address the known drawbacks. Actavis also pointed out that PENNSAID® 1.5% included all of the ingredients required by claim 12 of the '913 patent except for a thickener (the HPC), in addition to the claimed amounts of DMSO, propylene glycol, and water. As to the remaining limitations in claim 12, Actavis maintained that they were disclosed in the prior art. Actavis argued that all the changes were obvious optimizations of result-effective variables that produced a predictable result in relation to absorption, thickness, and drying times.

Horizon, on the other hand, argued that the changes made to PENNSAID® 1.5% were not routine optimizations, and that the results of the various changes could not be predicted by the prior art. According to Horizon, the prior art reflects that the field of topical pharmaceutical formulations is complex and unpredictable. And to arrive at the formulation recited in claim 12 of the '913 patent, Horizon maintains that a POSITA would have had to:

> (1) increase the diclofenac concentration from 1.5% to exactly 2%, (2) increase the concentration of ethanol from 11% to exactly the range of 23–29%, (3) add a thickening agent, (4) choose the thickening agent to be HPC, (5) identify the concentration of HPC to be exactly 2.5%, (6) select a viscosity range of between 500 and 5000 cps, and then (7) decide not to change the concentrations of DMSO or propylene glycol, but instead (8) remove or reduce glycerin and/or water to account for the increases in diclofenac, ethanol and thickening agent concentrations and still total 100%, and the [POSITA]

> would also have had to change the method of administration from 3–4 times per day to twice a day [despite knowing that increasing viscosity makes it harder for drug molecules to penetrate the skin.]

J.A. 15921–22.

Trial began on March 21, 2017, and continued until March 30, 2017. The parties filed post-trial submissions on April 20, 2017.

On May 12, 2017, the district court found that Actavis had not shown, by clear and convincing evidence, that claim 12 of the '913 patent is invalid for obviousness. On May 22, 2017, the district court entered a final judgment consistent with its holdings and conclusions in the *Markman* order, the summary-judgment order, and the post-trial findings of fact and conclusions of law. Since claim 12 of the '913 patent was found to be nonobvious and Actavis had stipulated to infringement of that claim if it was deemed not invalid at trial, the district court ordered that Actavis be enjoined from engaging in the commercial use, offer for sale, or sale of its ANDA product until the expiration of the '913 patent.

Horizon appeals and Actavis cross-appeals the district court's final judgment. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We first address Horizon's appeal and then Actavis's cross-appeal.

I. Horizon's Appeal

Horizon's appeal proceeds on two fronts. First, Horizon contests the district court's holding on claim construction that the terms "impurity A"; "degrades at less than 1% over 6 months"; and "consisting essentially of" are indefinite. Second, Horizon challenges the district court's holding, on

summary judgment, that Actavis's ANDA label did not induce infringement. For the reasons below, we affirm.

A. Indefiniteness

We review indefiniteness determinations de novo. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014). A claim is invalid for indefiniteness if its language, read in light of the specification and prosecution history, "fail[s] 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). General principles of claim construction apply to indefiniteness allegations. *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1377–78 (Fed. Cir. 2015). Accordingly, we review a district court's determinations of subsidiary facts based upon extrinsic evidence for clear error, and those based upon intrinsic evidence (the patent claims, specification, and prosecution history) de novo. *Id.*

The district court found that a POSITA would not have understood, with reasonable certainty, the scope of the claims reciting (1) "impurity A," (claim 4 of the '913 patent);[4] (2) a formulation that "degrades at less than 1% over 6 months" (asserted claims of the '613 patent and claims 10–11 and 19 of the '591 patent); and (3) a formulation "consisting essentially of" specified ingredients (asserted claims of the '838, '304, '305, and '784 patents and claims 12–15, 17, 19, and 24–25 of the '591 patent). It thus held that those claims were indefinite. We address each of those conclusions in turn.

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[4] As noted above, claim 12 of the '913 patent proceeded to trial. Of the asserted claims of the '913 patent, only claim 4 was implicated by the district court's claim construction and indefiniteness determination.

1. "Impurity A"

Claim 4 of the '913 patent recites a "topical formulation produc[ing] less than 0.1% [of] impurity A after 6 months at 25° C[] and 60% humidity." '913 patent col. 30 ll. 22–24. The district court concluded that "impurity A" is indefinite because a POSITA would not know, with reasonable certainty, the identity of the substance as claimed. We agree.

The term "impurity A" only appears in claim 4 and Example 6 of the '913 patent. Example 6 examines "the stability of the compositions of the present invention . . . at room temperature over a six month period." '913 patent col. 25 ll. 36–38. To do so, the example refers to a study where samples were placed into sealed plastic screw cap bottles and then stored at 25°C and 60% humidity for six months. *Id.* col. 25 ll. 47–49. After six months of storage, "the samples were tested for impurities by high performance liquid chromatography (HPLC)." *Id.* col. 25 ll. 49–51.

According to Example 6, this test revealed two unexpected findings: (1) that the composition of the invention contained a higher concentration of the active agent while resulting in a "lower concentration of a degradation impurity"; and (2) "that compositions using hydroxypropylcellulose (HPC) as the gelling agent had a significantly lower quantity of this impurity as compared to compositions made using carbomer gelling agents." *Id.* col. 25 ll. 38–46. In discussing the results of the study, the example refers to "an impurity, termed 'impurity A,' [which] was seen to elute at about 6.6 minutes in varying amounts for the various [tested] compositions." *Id.* col. 25 ll. 54–56. Table 13

shows the percentage of "impurity A" in relation to the tested compositions:

TABLE 13

Composition	Percent "impurity A" after 6 months of storage (wt/wt)
1.5% diclofenac sodium as a comparative liquid formulation solution	0.034%
2.0% diclofenac sodium in 0.9% Carbopol gel	0.09%
2.0% diclofenac sodium in 3.5% HPC gel	0.02%

Id. col. 25 ll. 57–66.

The example goes on to remark that the appearance of "a lower percentage of 'impurity A'" in the formulation "containing 3.5% HPC shows a higher degree of stability." *Id.* col. 26 ll. 1–5. It also states that the "reduction in the level of impurity A" in the HPC gel formulation, as compared to the formulation containing 0.9% Carbopol, shows that the former "is more stable than" the latter. *Id.* col. 26 ll. 7–11. Because of that, it concludes that "the present invention provides improved stability," which is evidenced by the "degrad[ation of] less than 0.034% or 0.09%" over the six-month period. *Id.* col. 26 ll. 11–16. Lastly, the example notes that "the amount of 'impurity A' found [was] . . . well below [the] limits that would require additional nonclinical testing of the impurity." *Id.* col. 26 ll. 16–19.

Although the specification does not define "impurity A," Horizon argues that a POSITA would understand the term to mean "USP Related Diclofenac Compound A." ("USP Compound A"). According to Horizon, a POSITA versed in the pertinent prior art would be able to ascertain the meaning of "impurity A" based on the intrinsic evidence. It is undisputed that the intrinsic evidence does not

explicitly refer to USP Compound A, or its chemical formulation, in relation to "impurity A." Still, Horizon maintains that, consulting the available pharmacopeias at the time, a POSITA would know "impurity A" refers to a specific impurity of diclofenac sodium. Horizon posits that because the specification refers to "impurity A" as a degradation of diclofenac sodium, which is the only component of the inventive formulation with a known impurity, a POSITA would know this term refers to "USP Related Diclofenac Compound A RS."

Actavis argues that the specification does not provide any clues as to the identity of "impurity A," which implies that "impurity A" is an unknown impurity. According to Actavis's expert, a POSITA reading the specification would read "impurity A" as referring to an unknown impurity because the specification: (a) does not disclose the chemical name of the impurity, which would be expected if such were known; (b) uses quotes to refer to "impurity A," suggesting that it is not the formal name of a known impurity; and (c) justifies not conducting additional tests to identify the impurity merely because it occurs in low amounts. Actavis contends that the only relevant disclosure in the specification about "impurity A" is in relation to Example 6. But, citing to its expert's declaration, Actavis maintains that the information in Example 6 is insufficient to allow a POSITA to determine the identity of "impurity A." For instance, Actavis's expert opined that the specification offers no information about the HPLC procedure used, including the column type, mobile solvent, and temperature used for the HPLC analysis reported. Moreover, Actavis contends that Example 6's observation that the amount of "impurity A" is so low that no "additional nonclinical testing" is required implies further testing was necessary to ascertain the identity of "impurity A."

As to Horizon's reliance on pharmacopeias, Actavis argues that the district court did not clearly err in rejecting Horizon's view on what a POSITA would have surmised

from those pharmacopeias. Actavis points out that the specification never mentions USP Diclofenac Related Compound A RS, which is a degradation of the active ingredient. Actavis also states that the claims refer to the degradation of the entire formulation—including other excipients (inactive ingredients)—as opposed to the degradation of the diclofenac sodium, the active ingredient. Actavis argues that even in light of the pharmacopeias, there is considerable doubt as to whether a POSITA would read "impurity A" to mean an impurity of the formulation as opposed to that of the active ingredient.

We find no error in the district court's conclusion that "impurity A" is indefinite. First, we look to the language of the claims to evaluate if the meaning of "impurity A" is reasonably clear. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1363 (Fed. Cir. 2018) ("We look first to the language of the claim to determine whether the meaning of [the term] is reasonably clear."). Claim 4 of the '913 patent depends upon claim 1. Claim 1 recites:

> 1. A topical formulation comprising:
>
> diclofenac sodium present at 2% w/w;
>
> DMSO present at about 40 to about 50% w/w;
>
> ethanol present at 23–29% w/w;
>
> propylene glycol present at 10–12% w/w;
>
> hydroxypropyl cellulose; and
>
> water to make 100% w/w,
>
> wherein the formulation has a viscosity of 500–5000 centipoise.

'913 patent col. 30 ll. 9–17. Claim 4 then recites the topical formulation of claim 1, wherein such formulation "produces less than 0.1% impurity A after 6 months at 25° C[] and

60% humidity." *Id.* col. 30 ll. 22–24. Although Horizon attempts to tie "impurity A" to diclofenac sodium, Actavis is correct to point out that the claims do not support such a result. Claim 4 refers to the entire topical formulation of claim 1, which includes several other excipients. The claims thus do not make clear that "impurity A" refers to an impurity of diclofenac sodium.

Looking beyond the language of the claims, it is also undisputed that the written description contains no references to USP Compound A or its chemical name. Indeed, Horizon does not cite to any part of the specification, the claims, or the prosecution history that defines or directly connects "impurity A" to USP Compound A. The only part of the specification that uses the term "impurity A" is Example 6, which contains "[t]he only identity information provided for 'impurity A.'" J.A. 9. That information consists of "retention times derived from a high performance liquid chromatography ('HPLC')." *Id.* The specification, however, is devoid of other information about the conditions of the HPLC experiment, such as the column, the mobile phase, and the flow rate. Thus, the written description provides no clue as to the identity of "impurity A."

Next, we turn to extrinsic evidence. Horizon attempted to connect "impurity A" to USP Compound A through pharmacopoeias and its expert's opinion. The district court considered that evidence but found that Horizon's expert did not explain why a POSITA would know that the HPLC test in Example 6 was undertaken using a pharmacopoeia chromatographic system. The district court understood this to mean that the basis upon which Horizon's entire argument rests—that a POSITA familiar with pharmacopoeias would understand "impurity A," as used in Example 6, to be USP Compound A—is incorrect. We agree.

The district court emphasized that none of the "references relied upon by [Horizon's expert] . . . that use [a] pharmacopoeia chromatographic system omit the details of

the HPLC experiment . . . or identify USP Compound A by anything other than its actual chemical formula and/or structure." J.A. 11. Put differently, because the specification omits the details of the HPLC experiment—such as the column, the mobile phase, and the flow rate—a POSITA faced with this specification would not reasonably presume that Example 6 was undertaken using a pharmacopoeia chromatographic system. This outcome undermines Horizon's reliance on the pharmacopoeias to extrapolate meaning into "impurity A."

We see no clear error in the district court's determination, based upon the extrinsic evidence, that "impurity A" is indefinite when used in the context of Example 6, which lacks sufficient information about the HPLC procedure to enable a POSITA to ascribe meaning to "impurity A" with reasonable certainty. *See Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1371–72 (Fed. Cir. 2017) (finding that the district court did not clearly err in determining, based on extrinsic evidence, what a POSITA would understand "vitamin B12" to mean in a medical context); *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1343–44 (Fed. Cir. 2016) (finding that the district court did not clearly err in determining, based on extrinsic evidence, that a POSITA would measure viscosity at room temperature if no other temperature is specified); *Berkheimer*, 881 F.3d at 1363–64 (affirming district court's conclusion that "minimal redundancy" limitation was indefinite because the subsidiary finding of fact that a POSITA would not have known what the term meant as used in claim was not clearly erroneous). To be clear, we do not hold that a reference to an impurity is indefinite in all contexts, only that on this record, the term "impurity A" is indefinite.

2. "Degrades"

Claims 1–5, 9–19, and 22–24 of the '613 patent, and claims 10–11 and 19 of the '591 patent, recite a topical formulation that "degrades [by/at][5] less than 1% over 6 months" (the "degrades" term).[6] '613 patent col. 27 l. 7–col. 28 l. 55; '591 patent col. 27 l. 6–col. 28 l. 21. The district court found this term indefinite because the specification did not identify the means of degradation. We agree.

The district court's finding that the claims reciting the "degrades" term are indefinite follows from the indefiniteness determination about "impurity A." This is so because Horizon's proposed construction for the "degrades" term was "[l]ess than 1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months." J.A. 12, 883. Since "impurity A" is indefinite, it logically follows that another term, such as the "degrades" term, which relies on "impurity A" for its construction, must also be indefinite. Based on the district court's indefiniteness determination about "impurity A," which we affirm, we conclude that its finding about the "degrades" term should also be affirmed.

3. "Consisting Essentially Of"

Several of the claims in the formulation patents recite, either directly (via independent claims) or indirectly (via dependent claims), a formulation "consisting essentially of"

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[5] The '613 patent recites "degrades by" while the '591 patent recites "degrades at."

[6] Claim 24 of the '613 patent recites a formulation that degrades by less than "0.5% over 6 months." '613 patent col. 28 ll. 50–51.

various ingredients.[7] Claim 49 of the '838 patent is illustrative. It recites:

> 49. A topical formulation *consisting essentially of*:
>
> 1–2% w/w diclofenac sodium;
>
> 40–50% w/w DMSO;
>
> 23–29% w/w ethanol;
>
> 10–12% w/w propylene glycol;
>
> hydroxypropyl cellulose; and
>
> water to make 100% w/w, wherein the topical formulation has a viscosity of 500–5000 centipoise.

'838 patent col. 30 ll. 60–67 (emphasis added).

The dissent argues that the claimed formulation cannot be indefinite in light of the expressly listed ingredients of the invention. Dissent Op. at 5. The dissent's position, however, would render the claim meaningless because it would have us read the term "essentially" out of the phrase "consisting essentially of," resulting in the separate and distinct claim phrase, "consisting of." This reading would be contrary to the well-established "principle that claim language should not [be] treated as meaningless." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006); *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 908 (Fed. Cir. 2005) (rejecting the district court's construction of the claim because it "reads out the essence of the claim limitation 'substantially flattened' as it

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[7] The relevant claims of the formulation patents are claims 49–52 and 55–61 of the '838 patent; claims 12–15, 17, 19, and 24–25 of the '591 patent; claims 2–5 and 8–11 of the '304 patent; claims 2–5 and 9–12 of the '305 patent; and claims 2–5 and 9–12 of the '784 patent.

equates 'flattened' with 'flat'"); *Application of Sabatino*, 480 F.2d 911, 913 (CCPA 1973). Here, the dissent reads out the term "essentially" so as to render the claim term to "consists of" or simply "consists."

The phrase "consisting essentially of" has a distinct meaning within our jurisprudence. It is a transition phrase often used to signal a partially open claim. *PPG Indus.*, 156 F.3d at 1354. The phrase serves as a middle ground between closed-ended claims using the phrase "consisting of" and open-ended claims using the phrase "comprising." *Id.*; *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). Accordingly, a drafter will generally include the phrase "consisting essentially of" before (a) a list of ingredients when dealing with a composition claim, or (b) a series of steps when dealing with a process claim. *PPG Indus.*, 156 F.3d at 1354. By doing so, "the drafter signals that the invention necessarily includes the listed ingredients [but] is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *Id.* Put differently, "[t]he phrase 'consisting essentially of' . . . permit[s] inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" *AK Steel*, 344 F.3d at 1239.

In light of our case law, the district court considered "consisting essentially of" in accordance with its legal meaning: "consisting of only the specified materials and those that do not materially affect the basic and novel properties of the claimed invention." J.A. 17. The parties do not dispute the legal meaning adopted by the district court about the phrase "consisting essentially of." Instead, the parties' dispute focuses on the basic and novel properties of the formulation patents. These properties are implicated by virtue of the phrase "consisting essentially of," which allows unlisted ingredients to be added to the formulation so long as they do not materially affect the basic and novel properties.

The district court held that the specification of the formulation patents identified five basic and novel properties: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. J.A. 23. Although Actavis maintains that the specification does not identify these characteristics as important enough to be considered basic and novel properties, we are unpersuaded.

The specification adequately identifies each of these properties by separate subheadings in the section titled "Characteristics of the Gel Formulation." '838 patent col. 9 l. 1–col. 10 l. 47. That section includes five subheadings: (a) "Transdermal Flux"; (b) "Viscosity"; (c) "Stability"; (d) "Drying Time"; and (e) "Pharmacokinetics." *Id.* Each subheading not only identifies the specific characteristic but also includes relevant discussion about its importance. The specification further highlights these features as advantageous over prior art, stating that the inventive formulation "display[s] a better drying time, higher viscosity, increased transdermal flux, and greater pharmacokinetic absorption," in addition to providing other advantages such as "favorable stability." *Id.* col. 4 ll. 21–32. With these particular aspects noted, the specification then states that the inventive formulation "provide[s] superior means for delivery of diclofenac sodium through the skin for the treatment of osteoarthritis." *Id.* col. 4 ll. 36–39. The district court thus correctly concluded that the intrinsic record identifies these characteristics as the basic and novel properties.

Next, we turn to whether the *Nautilus* definiteness standard applies to the basic and novel properties of an invention. In *Nautilus*, the Supreme Court held that "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." 572 U.S. at 901. The district court evaluated the basic and

novel properties under this definiteness standard. Horizon maintains that was legal error.

Horizon argues that the *Nautilus* definiteness standard focuses on the claims and therefore does not apply to the basic and novel properties of the invention. This argument, however, is misguided. By 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. The use of "consisting essentially of" implicates not only the items listed after the phrase, but also those steps (in a process claim) or ingredients (in a composition claim) that do not materially affect the basic and novel properties of the invention. Having 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. Indeed, this contravenes the legal meaning associated with the phrase "consisting essentially of." And a holding to the contrary would promote the innovation-discouraging "zone of uncertainty" that the Supreme Court has warned against. *See Nautilus*, 572 U.S. at 911 (rejecting the "not amenable to construction or insolubly ambiguous" definiteness standard in favor of one that fosters the public-notice function of the definiteness requirement); *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942) ("The statutory requirement of particularity and distinctness in claims is met only when they . . . clearly circumscribe what is foreclosed from future enterprise. A zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field."). Notably, the phrase "consisting essentially of" is not per se indefinite. Indeed, a patentee can reap the benefit of claiming unnamed ingredients and steps by employing the phrase

"consisting essentially of" so long as the basic and novel properties of the invention are definite.

Horizon attempts to cast the issue about the bounds of the basic and novel properties as one that should not be addressed at the claim construction stage, arguing this court considers those properties solely as factual determinations of validity and infringement. *See* Appellant Br. 41–42. But Horizon's view about the role of the basic and novel properties disregards one of the cornerstones of the definiteness requirement: to afford clear notice of what is being claimed so as to apprise the public of what is still open to them. *Nautilus*, 572 U.S. at 909.

The Supreme Court has repeatedly emphasized why the definiteness requirement demands clear notice of what is being claimed. In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, the Court explained:

> The patent laws "promote the Progress of Science and useful Arts" by rewarding innovation with a temporary monopoly. U.S. Const., Art. I, § 8, cl. 8. The monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not. For this reason, the patent laws require inventors to describe their work in "full, clear, concise, and exact terms," 35 U.S.C. § 112, as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights.

535 U.S. 722, 730–31 (2002). Accordingly, "[t]he limits of a patent must be known" because the goal of the definiteness requirement is "to guard against unreasonable advantages

to the patentee and disadvantages to others arising from uncertainty." *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938). That is why "inventor[s] must inform the public [about] the limits of the monopoly asserted, [i.e., the patented invention,] so that it may be known which features may be safely used or manufactured without a license and which may not." *Id.* (internal quotation marks omitted).

Having determined that the basic and novel properties of an invention are part of the scope of the claims in this case, it follows that those basic and novel properties, "when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art." *See Interval Licensing*, 766 F.3d at 1371; *see also Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005) ("Some objective standard must be provided in order to allow the public to determine the scope of the claimed invention."). That the basic and novel properties may not be precise does not automatically render them indefinite. *See Seattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984). Instead, the basic and novel properties must be sufficiently definite so as to inform, with reasonable certainty, a POSITA of their scope within the context of the invention. *Nautilus*, 572 U.S. at 901.

Two questions arise when claims use the phrase "consisting essentially of." One question focuses on definiteness: what are the basic and novel properties of the invention? The other question focuses on infringement: does a particular unlisted ingredient materially affect those basic and novel properties? There certainly may be circumstances where it will be up to a fact-finder to determine whether an unlisted ingredient has a material effect on the basic and novel properties of the invention. Our analyses in *PPG Industries* and *AK Steel* of patents using the term "consisting essentially of" in the claims is instructive as to this distinction.

In *PPG Industries*, we evaluated a patent directed to a green-tinted glass with specific light transmittance characteristics. 156 F.3d at 1352. The patent claimed that the composition of the glass "consist[ed] essentially of" a list of chemical ingredients. *Id.* Iron sulfide was not listed in the claims and was present in the accused product. *Id.* at 1354. The alleged infringer defended on that basis. At trial, since the claims used the phrase "consisting essentially of," the district court instructed the jury that the claimed glass included other ingredients not specifically identified in the claim so long as those unlisted ingredients did not have a material effect on the basic and novel properties of the glass. *Id.* at 1354. The parties had agreed that the basic and novel properties of the claimed glass were color, composition, and light transmittance. *Id.* We held that, because "the patent is silent about iron sulfide and about what constitutes a material effect on the properties of the glass," it was proper for "the jury to determine whether the amounts of iron sulfide in [the accused glass] have a material effect on the basic and novel characteristics of the glass." *Id.* at 1357.

In *AK Steel*, we dealt with patents directed to hot-dip aluminum-coated stainless steel. 344 F.3d at 1236. One of the patents at issue used the phrase "consisting essentially of aluminum" in the claims. *Id.* at 1237. The district court construed the phrase to permit only up to about 0.5% silicon. *Id.* at 1238. Since the accused product included aluminum and 8.0%–8.5% silicon, the district court granted summary judgment of noninfringement. *Id.* We affirmed, noting that the patent clearly identified "good wetting" as the goal of the invention and as the distinguishing feature from the prior art. *Id.* at 1239–40. This was a basic and novel property. The specification also stated that having silicon in excess of 0.5% by weight in an aluminum coating did not achieve the goal of "good wetting." *See id.* In other words, 0.5% silicon by weight served as a threshold, and

anything above it would not achieve the goal of "good wetting." We held that *PPG Industries* did not compel the district court to submit the issue of whether more than 0.5% silicon materially alters the basic and novel properties of the invention to the jury. *Id.* at 1240–41. We explained that the specification in *PPG Industries* was silent about iron sulfide and what constitutes a material effect on the properties of the glass. *Id.* at 1240. But, unlike *PPG Industries*, the specification at issue in *AK Steel* was far from silent about silicon and its material effect on the properties of the invention, particularly where the specification identified having silicon in excess of 0.5% by weight in aluminum coating as contravening the goal of "good wetting." *Id.* The district court was thus correct to construe the claims as not encompassing steel coated with aluminum containing more than about 0.5% silicon, and then grant summary judgment of noninfringement because the accused product contained 8.0%–8.5% silicon. *Id.* at 1240–41.

In relation to this case, the crucial teachings from both *PPG Industries* and *AK Steel* is that 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 then consider if the intrinsic evidence establishes what constitutes a material alteration of those properties. The definiteness inquiry focuses on whether a POSITA is reasonably certain about the scope of the invention. Indeed, if 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. To determine if an unlisted ingredient materially alters the basic and novel properties of an invention, the *Nautilus* definiteness standard requires that the basic and novel properties be known and definite. Accordingly, in this case, the district court did not err in considering the definiteness of the basic and novel properties during claim construction.

Lastly, we address whether the district court erred in determining that the basic and novel property of "better drying time" was indefinite. We conclude that it did not.

The section of the specification listing the basic and novel properties of the invention includes a subheading for "Drying Time." '838 patent col. 10 l. 5. Under that subheading, the specification explains that the compositions of the invention "dry quicker" than previously disclosed compositions. *Id.* col. 10 ll. 6–10. In support, the specification discloses results from two tests: an *in vivo* test and an *in vitro* test.

As to the *in vivo* test, the specification states that "[t]he drying time difference is evident when equal amounts of the two products are tested on opposite limbs. Within thirty (30) minutes the compositions of the invention are almost completely dry whereas a significant amount of the previously described liquid formulation remains." *Id.* col. 10 ll. 15–21. No other data is provided about the test.

As to the *in vitro* test, the specification notes that "drying times" were compared "more quantitatively" by conducting side-by-side comparisons. *Id.* col. 10 ll. 22–23. To do so, the inventors "measured the residual weight of formulations by placing equal amounts (100 mg) of a prior art formulation and compositions of the invention in weighing dishes . . . and weighing the amount remaining over time." *Id.* col. 10 ll. 23–27. According to the specification, under this methodology "a difference is immediately noticeable, and becomes dramatically different by 4 hours." *Id.* col. 10 ll. 27–29. The *in vitro* test corresponds with Example 5, and Table 12 reflects the data from the test. Example 5, entitled "Comparison of Drying Time/Residual Weight of a Comparative Liquid Formulation Solution Versus the Corresponding Gel," reveals that the prior art formulation was compared to three gel compositions which are embodiments of the invention. *See id.* col. 21 l. 38–col. 22 l. 49.

Table 12 provides information about the percentage of the remaining weight as follows:

	% 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

Id. col. 23 ll. 17–27.

The district court found that the two different methods for evaluating "better drying time" do not provide consistent results at consistent times. J.A. 26. On the one hand, the *in vivo* test noted that after thirty minutes the compositions of the invention are "almost completely dry" while a "significant amount" of the prior art formulation remained. J.A. 24–27. But on the other hand, when the results of the *in vitro* test are reviewed at the thirty-minute mark, only two of the formulations exhibit "better drying time." *Id.* As reflected in Table 12, at thirty minutes the prior art liquid comparative showed 95.6% of its weight remaining, whereas the "F971" inventive formulation showed 100% of its weight remaining. J.A. 25–26. After highlighting these inconsistencies, the district court noted that the prosecution history failed to inform as to the appropriate time frame under which to evaluate the drying rate. J.A. 27. The district court also found persuasive the testimony of Actavis's expert that a POSITA would not know under what standard to evaluate the drying rate. *Id.* Accordingly, the district court concluded that the basic and

novel property of "better drying rate" was indefinite, and consequently, that the term "consisting essentially of" was likewise indefinite. *Id.*

On appeal, Horizon argues that the district court improperly conflated "drying rate" with "better drying time." According to Horizon, "drying rate" refers to "how quickly [a formulation] dries" while "drying time" refers to "how long [a formulation] takes to dry." Appellant Br. 49. In light of this distinction, Horizon maintains that the specification's descriptions of the results of the *in vivo* test and *in vitro* test are not in conflict. Horizon asserts that a POSITA would understand that the time points earlier than 4 hours in the *in vitro* test do not reflect drying time, and instead, they reflect drying rates that can change over time. Horizon argues that the district court failed to comprehend the differences between the two tests.

In response, Actavis contends that the patent uses the concepts of "drying time" and "drying rate" interchangeably, with both terms apparently intended to refer to the residual weight of the formulation left as time progresses. But Horizon challenges that assertion, stating that the "specification differentiates these two concepts, referencing 'drying time' as a characteristic of the inventive formulations, and then separately discussing drying rate in relation to the speed ('more rapid,' 'quicker,' or 'faster') of drying." Appellant Reply Br. 61. We find Horizon's proposed distinction unpersuasive in light of the specification.

Example 5, the *in vitro* test, compared "drying time" in relation to the residual weight of a given formulation. Its stated purpose was to "evaluate . . . drying time." '838 patent col. 21 l. 45. Throughout Example 5, the specification tethers a "dryness" evaluation to the residual weight of a formulation in order to show the improved characteristic over the prior art. *See id.* col. 22 ll. 7–10 (stating that "one would have expected the liquid formulation to lose weight

more quickly, and thus have a shorter drying time"). Beyond that, the basic point raised by the district court remains: the results are inconsistent. Referring to the results in Example 5, the specification states that "even within the first five minutes, the three gel formulations displayed *more rapid drying* than the liquid formulation." *Id.* col. 21 ll. 63–65 (emphasis added). Regardless of the distinction Horizon attempts to draw, this statement stands for the proposition that, at the five-minute mark, the three inventive formulations are *drier* than the prior art formulation. So, it follows that according to the specification's clear language, the inventive formulations displayed better drying time when compared at five minutes. But, as the district court pointed out, the data is inconsistent with the specification's statement about better drying at five minutes (as stated in the *in vitro* test) or at thirty minutes (as compared to the *in vivo* test). At both of those marks, Table 12 reflects that inventive gel "F971" retained a larger percentage weight than the prior art. Only at the four-hour mark does the inventive gel "F971" reflect a lower percentage than the prior art comparator.

"[A] claim is indefinite if its language might mean several different things and no informed and confident choice is available among the contending definitions." *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015) (internal quotations marks omitted). Here, an evaluation of the specification reveals inconsistencies about the basic and novel property of "better drying time." Two tests are disclosed, but those tests do not provide consistent results upon which a POSITA would be able to evaluate "better drying time." Consequently, we conclude that the district court did not err in its determination that a POSITA would not know under what standard to evaluate the drying rate of the invention, thus rendering the basic and novel property of "better drying rate" indefinite.

In sum, we hold that the district court did not err in: (a) defining the basic and novel properties of the formulation patents; (b) applying the *Nautilus* definiteness standard to the basic and novel properties of the formulation patents; and (c) concluding that the phrase "consisting essentially of" was indefinite based on its finding that the basic and novel property of "better drying time" was indefinite on this record. To be clear, we do not hold today that so long as there is any ambiguity in the patent's description of the basic and novel properties of its invention, no matter how marginal, the phrase "consisting essentially of" would be considered indefinite. Nor are we requiring that the patent owner draft claims to an untenable level of specificity. We conclude only that, on these particular facts, the district court did not err in determining that the phrase "consisting essentially of" was indefinite in light of the indefinite scope of the invention's basic and novel property of a "better drying time."[8]

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[8] The dissent states that "[i]t is hard to imagine a clearer statement than a list of the ingredients that the claimed formulation 'consists essentially of.'" Dissent Op. at 5. It 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. *PPG Indus.*, 156 F.3d at 1354.

Here, the patentee, however, chose to use the distinct and separate phrase, "consisting *essentially* of." In so choosing, the patentee can now assert its claim against products containing ingredients nowhere listed in the patent claim, an option foreclosed under the phrase "consisting of." *See, e.g.*, *AK Steel*, 344 F.3d at 1239 ("consisting

B. Induced Infringement

We review the district court's grant of summary judgment de novo. *Frolow v. Wilson Sporting Goods Co.*, 710 F.3d 1303, 1308 (Fed. Cir. 2013) (citing *Nicini v. Morra,* 212 F.3d 798, 805 (3d Cir. 2000) (en banc)). Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). The nonmovant's evidence is to be believed and all justifiable inferences are to be drawn in his favor. *Frolow*, 710 F.3d at 1308.

The district court granted summary judgment in relation to the asserted claims of the method-of-use patents[9] on the basis that Horizon failed to show that Actavis's label induces a use of its ANDA product that directly infringes those claims. We review Actavis's ANDA label in relation to the asserted claims of the methods-of-use patents to evaluate if the district court erred in concluding that Actavis's label does not induce infringement of those particular claims.

Actavis's ANDA product, diclofenac sodium topical solution 2%, is a generic version of Horizon's PENNSAID®

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essentially of aluminum" asserted against product containing aluminum and silicon). This flexibility afforded to patentee underscores the importance of our holding today: that when the patentee choses to use the phrase "consisting essentially of," the underlying basic and novel properties of that invention should be sufficiently definite in scope in order to afford clear notice of the claim's bound. *Nautilus*, 572 U.S. at 909.

[9] Claims 10, 11, 15, and 17 of the '450 patent, claim 14 of the '078 patent, and claims 3, 11, and 13 of the '110 patent.

2%. Both products are directed to the treatment of osteoarthritis pain on the knees. In relevant part, Actavis's label includes the following:

> The recommended dose is 2 pump actuations on each painful knee, 2 times a day. (2)
>
> - Apply diclofenac sodium topical solution, to clean, dry skin. (2.1)
> - Dispense 40 mg (2 pump actuations) directly onto the knee or first into the hand and then onto the knee. Spread evenly around front, back and sides of the knee. (2.1)
>
> . . . .
>
> - *Wait until area is completely dry before covering with clothing or applying sunscreen, insect repellent, cosmetics, topical medications, or other substances.* (2.2)
>
> . . . .
>
> - Avoid wearing clothing over the diclofenac sodium topical solution-treated knee(s) until the treated knee is dry.
> - Protect the treated knee(s) from natural and artificial sunlight.
> - *Wait until the treated area is dry before applying sunscreen, insect repellant, lotion, moisturizer, cosmetics, or other topical medication to the same knee you have just treated with diclofenac sodium topical solution.*
> - Until the treated knee(s) is completely dry, avoid skin-to-skin contact between other people and the treated knee(s).

J.A. 5873, 5876 (emphasis added) (numbers in parentheses indicating cross references: e.g., 2.1 indicating "general

dosing instructions" and 2.2. indicating "special precautions").

It is undisputed that Actavis's label is substantially similar to Horizon's; the primary difference between the two labels is that Horizon's label refers to "PENNSAID" instead of "diclofenac sodium topical solution" or "diclofenac sodium."

Turning to the method-of-use patents, claim 10 of the '450 patent is illustrative of the asserted method-of-use claims. It recites:

> 10. A method for applying topical agents to a knee of a patient with pain, said method comprising:
>
> > applying a first medication consisting of a topical diclofenac preparation to an area of the knee of said patient to treat osteoarthritis of the knee of said patient, wherein the topical diclofenac preparation comprises a therapeutically effective amount of a diclofenac salt and 40–50% w/w dimethyl sulfoxide;
> >
> > waiting for the treated area to dry;
> >
> > subsequently applying a sunscreen, or an insect repellant to said treated area after said treated area is dry, wherein said step of applying a first medication does not enhance the systemic absorption of the subsequently applied sunscreen, or insect repellant;
> >
> > and wherein said subsequent application occurs during a course of treatment of said patient with said topical diclofenac preparation.

'450 patent col. 73 l. 36–col. 74 l. 10.

The district court evaluated Actavis's label vis-à-vis the claims of the method-of-use patents and noted that the dispute between the parties centered around the warning in Actavis's label to wait until the treated area is dry before covering it or applying another substance. Because Horizon alleged that the warning in Actavis's label would induce infringement of its method-of-use patents, the district court evaluated the claims, stating that Horizon's claimed methods provide three sequential instructions. J.A. 52–53. First, the user applies the medication to the knee. Second, the user waits for the treated area to dry. And third, the user subsequently applies sunscreen or insect repellant.[10] With this framework in mind, the district court found that "Actavis's proposed label does [no] more than simply permit, rather than require or direct, the post-product application of sunscreen, insect repellant, or a second topical medication." J.A. 58. So even if at some point a user applies one of the items claimed in step three of the method-of-use claims to his or her knee, the district court explained that "permission does not amount to encouragement because those items are just three examples of what a patient might wish to apply to his knee after treatment, if anything is to be applied at all." J.A. 59. The district court thus concluded that Actavis's label was insufficient to create a material dispute of fact as to whether the label suggests an infringing use. J.A. 59–60.

On appeal, Horizon argues that the district court erred in finding that Actavis's labeling did not induce infringement of the method-of-use patents. Horizon maintains that Actavis's labeling tracks closely with the asserted claims, thereby reflecting Actavis's specific intent to induce

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[10] For the '078 patent, the third step consists of applying a second medication, and for the '110 patent it consists of applying sunscreen, an insect repellant, or a second medication. J.A. 53.

infringement. Although Horizon recognizes that not every user will need to apply sunscreen, insect repellant, or another topical medication, it contends that, when such need arises, Actavis's instruction will lead to an infringing use. Horizon also points to a warning in Actavis's labeling that cautions patients to avoid exposure to natural or artificial sunlight on the treated knees,[11] arguing this reflects that application of sunscreen is medically necessary. Lastly, Horizon contends that material issues of fact preclude summary judgment. Specifically, Horizon cites to its expert's testimony and states that the district court should have viewed it in Horizon's favor and thus denied Actavis's motion.

Actavis disputes Horizon's proposition that there are material issues of fact that precluded summary judgment. Actavis argues that its proposed label does not induce infringement because, unlike the method-of-use patents, its label does not promote the application of a second topical agent after application of the diclofenac sodium gel. Actavis maintains that its label never affirmatively instructs the patient to apply anything after the diclofenac sodium gel; the label merely permits applying a second topical agent after the patient waits for the diclofenac sodium to dry. Its label, therefore, does not contain any instruction that induces infringement. Instead, Actavis states that the label warns patients that if they choose to apply a second topical agent, they should take the precaution of waiting

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[11] Section 5.14 of Actavis's labeling, entitled "Sun Exposure," provides: "Instruct patients to avoid exposure to natural or artificial sunlight on treated knee(s) because studies in animals indicated topical diclofenac treatment resulted in an earlier onset of ultraviolet light-induced skin tumors. The potential effects of diclofenac sodium topical solution on skin response to ultraviolet damage in humans are not known." J.A. 5881.

for the diclofenac sodium gel to dry. Because Horizon's only evidence of inducement depends upon Actavis's label, Actavis contends that there are no material issues of fact and that the district court correctly resolved the matter on summary judgment.

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To prove inducement, a plaintiff must present evidence of active steps taken to encourage direct infringement; mere knowledge about a product's characteristics or that it may be put to infringing uses is not enough. *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630–31 (Fed. Cir. 2015). The focus is not on whether the instructions describe the mode of infringement, but rather on whether the "instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent." *Id.* at 631 (emphasis omitted). In ANDA cases, when a plaintiff attempts to draw intent from the label, we examine whether the proposed label "encourage[s], recommend[s], or promote[s] infringement." *Id.* Merely describing the infringing use, or knowing of the possibility of infringement, will not suffice; specific intent and action to induce infringement must be shown. *Id.*

The patented method here requires three distinct steps. The user must: (1) apply the inventive formulation, (2) wait for the area to dry, and (3) apply sunscreen, insect repellant, or a second topical medication. The instructions in Actavis's label, however, only require the first step of this method, nothing else. Moreover, Actavis's label is broader than step three of Horizon's claimed method. For example, beyond warning the user about waiting for the treated area to be completely dry before covering it with sunscreen, insect repellent, or another topical medication, Actavis's label also warns about clothing, cosmetics, lotion, water, moisturizer, and other substances. J.A. 5873, 5876, 5898. The warning, then, operates in an "if/then" manner:

if the user wants to cover the treated area with clothing or apply another substance over it, *then* the patient should wait until the area is dry. J.A. 53. This does not encourage infringement, particularly where the label does not require subsequent application of sunscreen, insect repellant, or a second medication.

We are also unpersuaded by Horizon's reliance on its expert's opinion to maintain that there are material issues of fact that prevent summary judgment. Horizon concedes that its expert recognized that not all patients who follow the instructions in Actavis's label will engage in an infringing use by applying sunscreen, insect repellant, or a second medication. *See* Appellant Br. 29–30. And the "mere existence of direct infringement . . . is not sufficient for inducement." *Takeda*, 785 F.3d at 631. Instead, our inquiry focuses on whether the instructions reflect an "affirmative" or "specific intent to encourage infringement." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009). The district court examined Actavis's label in detail and concluded that there can be no material dispute that the instructions do not reflect specific intent to induce. The district court found that the label merely provided guidance to patients about what to do if the patent desired to have anything come into contact with the knee after application of the medication.

The fact that Actavis's label does not require subsequent application of other products reflects that the product has "substantial noninfringing uses, [and] intent to induce infringement cannot be inferred even [if Actavis] has actual knowledge that some users of its product may be infringing the patent." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). Horizon's evidence, viewed in the light most favorable to it, establishes that some users might infringe. The evidence, however, does not establish that "the proposed label instructs users to perform the patented method." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

The district court did not err in granting summary judgment of noninfringement in Actavis's favor.

II. Actavis's Cross-Appeal on Obviousness

After a seven-day bench trial, the district court held that Actavis did not show, by clear and convincing evidence, that claim 12 of the '913 patent is invalid for obviousness. Actavis cross-appeals the nonobviousness determination. We review the ultimate legal conclusion about obviousness de novo and the underlying factual findings for clear error. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1354 (Fed. Cir. 2013).

Actavis's cross-appeal centers around the district court's statement that claim 12 of the '913 patent "was not a result of routine optimization of PENNSAID® 1.5% . . . because general principles and ranges of permissible concentrations would not have *predicted the exact formulation* and dosing frequency that resulted in PENNSAID® 2%." J.A. 15923 (emphasis added). Actavis argues that the district court erred by requiring that the prior art predict the exact formulation of the asserted claim.

To explain its obviousness theory, Actavis relied on a stereo receiver analogy drawn by its expert. Under that analogy, the various components of PENNSAID® 2% are like bass, treble, fade, and volume, among other things. Cross-Appellant Br. 69. In the analogy, the knobs of the stereo receiver correspond to various aspects of the formulation, such as the thickener that adjusts viscosity, the diclofenac sodium concentration that adjusts permeation rate/absorption, or the glycerine that adjusts drying rate. According to Actavis, if a POSITA wants to change one aspect of the formulation in a particular way, she may adjust the knobs upwards or downwards for the parameter corresponding to the desired change.

The district court found the analogy to be inconsistent with the complexity of the art, and more specifically, with the particular components of the formulation. J.A. 15925. The district court explained that Actavis's analogy failed to "differentiate between a system that allows independent change of one variable with little or no predictable or material effect on other variables and a system where the change to one variable must result in changes to the others." *Id.* While a drug formulator could be inspired by general knowledge and the prior art to adjust a certain variable, the district court found that the variables here interacted with each other in unpredictable ways. *See id.*

The district court credited Horizon's expert's (Dr. Bunge's) testimony that the inventive formulation was complex and that a POSITA would be challenged to predict relative ratios in order to achieve the desired goal of PENNSAID® 2%. J.A. 15926–27. The district court further highlighted the unpredictability of the results by crediting Dr. Bunge's testimony that Fick's law[12]—an established concept about drug permeation—could not predict what happens under the facts of this case, which involve a complex topical formulation that attempts to drive an active ingredient through human skin (a "formidable barrier" according to the district court's findings). J.A. 15929–32.

The district court also found that the combination of changes to the PENNSAID® 1.5% formulation were not obvious optimizations of result-effective "variables that would produce a predictable result, particularly as to the formulation's absorption, thickness, and drying time."

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[12] "Under Fick's First Law of Diffusion, a larger concentration of the drug in the topical formulation results in a larger concentration gradient, and leads to a greater permeation—or flux—rate of the drug through the skin." J.A. 15909.

J.A. 15933. The district court found that the variables involved in this case, including the components of the inventive formulation, interact in an unpredictable or unexpected way, such that the results emanating into PENNSAID® 2% were not obvious. J.A. 15933–36. The district court found that nothing in the prior art allowed a POSITA to find "the schematic or roadmap to a diclofenac gel effective at two doses a day." J.A. 15934. The district court thus held that "the combination of adjustments needed to change PENNSAID® 1.5% into PENNSAID® 2% was not predictable from the prior art." J.A. 15933.

We hold that the district court did not clearly err in its factual findings about the lack of predictability in relation to the changes made to PENNSAID® 1.5% and the teachings from the prior art. In light of the district court's factual findings, we hold that claim 12 of the '913 patent was nonobvious. We thus affirm the district court's nonobviousness conclusion and its determination that PENNSAID® 2% was not the result of routine experimentation such that a POSITA would have reasonably predicted the changes made to PENNSAID® 1.5%.

CONCLUSION

We have considered all remaining arguments but find them unpersuasive. For the foregoing reasons, we affirm the judgment of the district court.

AFFIRMED

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

HZNP MEDICINES LLC, HORIZON PHARMA USA, INC.,
Plaintiffs-Appellants

v.

ACTAVIS LABORATORIES UT, INC.,
Defendant-Cross-Appellant

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

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.

NEWMAN, *Circuit Judge*, concurring-in-part, dissenting-in-part.

This suit was brought pursuant to the Hatch-Waxman Act, based on Actavis' ANDA challenge to the HZNP

(Horizon) patents on the product PENNSAID® 2%, a formulation of the drug diclofenac sodium for topical application to treat osteoarthritis of the knee. Actavis stated to the FDA that its generic ANDA composition and method are within the Horizon patents, and Actavis' Paragraph IV certification led to this litigation in which Actavis challenges the validity and infringement of the Horizon patents. Trial was held in the district court.

On the issue of patent validity, the district court held the composition claims invalid, holding that the claim term "consisting essentially of" rendered the claims indefinite, in violation of 35 U.S.C. § 112(b). The panel majority agrees. The majority also holds that the knowledge of persons of skill in the field of the invention cannot fill any gap in proving the properties of compositions claimed in the "consisting essentially of" form. I respectfully dissent from these departures from long-established law and long-understood practice.

The district court held the method-of-use claims valid but not infringed. On the issue of infringement of these claims, Actavis conceded that the instructions in its ANDA label are identical to the method-of-use claimed in the Horizon patents. However, the district court held that, except for one claim, Actavis cannot be liable for induced infringement because the user might not follow the instructions on the label. The panel majority agrees. Again I respectfully dissent, for this holding is contrary to statute and precedent.

On Actavis' cross-appeal, the district court sustained the validity of claim 12 of U.S. Patent No. 9,066,913 ("the '913 patent"), and found infringement. The panel majority sustains that judgment. I join that aspect of the court's decision.

I start with brief reference to Actavis' cross-appeal, for the court's correct ruling on claim 12 of the '913 patent

points up the inconsistency and uncertainty spawned by today's decision.

I

ACTAVIS' CROSS-APPEAL

Following is claim 12 of the '913 patent, shown with the claims whose subject matter is incorporated by reference:

> 12. A method for treating pain due to osteoarthritis of a knee of a patient in need thereof, said method comprising:
> administering to the knee a topical formulation of claim 9,
> wherein the administration of the formulation is twice daily.
>
> 9. The topical formulation of claim 8, wherein the hydroxypropyl cellulose is present at 2.5% w/w.
>
> 8. The topical formulation of claim 1, wherein the DMSO is present at 45.5% w/w.
>
> 1. A topical formulation comprising:
> diclofenac sodium present at 2% w/w;
> DMSO present at about 40 to about 50% w/w;
> ethanol present at 23–29% w/w;
> propylene glycol present at 10–12% w/w;
> hydroxypropyl cellulose; and
> water to make 100% w/w,
> wherein the formulation has a viscosity of 500–5000 centipoise.

In the district court the only challenge to validity of claim 12 was on the ground of obviousness. Actavis stipulated to infringement. I flag the usage "comprising" in claim 1 above, for this is the identical composition for which "consisting essentially of" is today held to invalidate the composition claims on the ground of indefiniteness.

II

INDEFINITENESS

The claim definiteness requirement is codified at 35 U.S.C. § 112(b):

> § 112(b) *Conclusion.*—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

An illustrative claim held invalid based on the usage "consisting essentially of" is claim 49 of Horizon's U.S. Patent No. 8,252,838 ("the '838 patent"):

> 49. A topical formulation consisting essentially of:
> 1–2% w/w diclofenac sodium;
> 40–50% w/w DMSO;
> 23–29% w/w ethanol;
> 10–12% w/w propylene glycol;
> hydroxypropyl cellulose; and
> water to make 100% w/w, wherein the topical formulation has a viscosity of 500–5000 centipoise.

'838 patent, col. 30, ll. 60–67; Maj. Op. at 4, 21.

The usage "consisting essentially of" is not a ground of invalidity

The panel majority holds that the phrase "consisting essentially of" invalidates the composition claims for indefiniteness, Maj. Op. at 33, because the claims are rendered "open to unlisted ingredients that do not materially affect the basic and novel properties of the invention," *id.* at 22. The majority holds that "By 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.* at 24. That is not correct as a matter of claim construction, it is not the law of

patenting novel compositions, and it is not the correct application of section 112(b).

Definiteness of claiming requires that the subject matter for which patent protection is sought is clearly stated in the claim. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."); *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008) ("If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." (quoting *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001))). It is hard to imagine a clearer statement than a list of the ingredients that the claimed formulation "consists essentially of."

Both sides agree that there are no unlisted ingredients in the formulations claimed in these patents. However, the majority states: "Having 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." Maj. Op. at 24. This statement is contrary to long-standing law and practice, as summarized in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 908 (2014): "[I]n assessing definiteness, claims are to be read in light of the patent's specification and prosecution history. *See, e.g.*, *United States v. Adams*, 383 U.S. 39, 48–49 (1966) (specification); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 741 (2002) (prosecution history)."

When the properties of a composition are described in the specification, the usage "consisting essentially of" the

ingredients of the composition does not invalidate the claims when the properties are not repeated in the claims.

The property of better drying time and its measurement need not be included in composition claims "consisting essentially of" the listed ingredients

The panel majority affirms that "the phrase 'consisting essentially of' was indefinite based on [the district court's] finding that the basic and novel property of 'better drying time' was indefinite on this record." Maj. Op. at 33. The majority criticizes Example 5, headed "Comparison of Drying Time/Residual Weight of a Comparative Liquid Formulation Solution Versus the Corresponding Gel." '838 patent, col. 21, l. 38–col. 22, l. 49. Example 5 presents experimental details and the results of measuring drying time of samples *in vitro* in weighing dishes, and *in vivo* as applied directly to the knees.

The district court held that since two measures of drying time were in Example 5, "a POSA would not know under what standard to evaluate the drying rate of the claimed invention." Dist. Ct. Op. at 27 (J.A. 27). On this reasoning, the district court invalidated the composition claims for indefiniteness. The panel majority agrees, stating that "this prevented a POSITA from being able to have 'reasonable certainty' about the scope of the basic and novel properties of the invention, thereby rendering the term 'consisting essentially of' indefinite." Maj. Op. at 7.

Whatever the significance of drying time as an advantage of the claimed composition, recitation and measurement of this property in the specification does not convert the composition claims into invalidating indefiniteness because the ingredients are listed in the claims as "consisting essentially of."

The property of improved stability and its measurement need not be included in

composition claims "consisting essentially of" the listed ingredients

The majority also finds indefiniteness of "consisting essentially of" claims based on the property of stability of the claimed formulations. Longer shelf-life is stated to be an advantage of these products, and is demonstrated in Example 6 entitled "Comparison of Stability Characteristics of a Comparative Liquid Formulation Versus Diclofenac Sodium Gel Formulations." '913 patent, col. 25, l. 29–col. 26, l. 20. In Example 6, samples were stored for 6 months at 60% humidity and 25º C, and "the samples were tested for impurities by high performance liquid chromatography." *Id.*, col. 25, ll. 47–51. Example 6 tabulates the results, and concludes: "It was found that upon 6 months of storage, an impurity, termed 'impurity A', was seen to elute at about 6.6 minutes in varying amounts for the various compositions as shown in Table 13 below." '913 patent, col. 25, ll. 53–56; U.S. Patent No. 8,563,613, col. 22, ll. 52–55.

The majority holds that the "consisting essentially of" claims are indefinite because Example 6 does not state the chemical name of impurity A and does not provide full details of the chromatography procedure. Horizon responds that impurity A is described in the US Pharmacopoeia as impurity A of diclofenac (USP Diclofenac Related Compound A RS), and that persons of skill in this field would know of this resource; an expert witness so testified.

Despite Example 6 and its detailed measurement of the degradation product impurity A, the majority states that "neither the claims nor the specification disclose the means to evaluate degradation," Maj. Op at 6. The specification describes and exemplifies the stability to degradation by measuring the appearance of Impurity A in various conditions. The criticism is untenable. *See One-E-Way, Inc. v. Int'l Trade Comm'n*, 859 F.3d 1059, 1063 (Fed. Cir. 2017) ("As long as claim terms satisfy this test [of understanding

by persons of skill in the field], relative terms and words of degree do not render patent claims invalid.").

My colleagues also state that "[t]he claims . . . do not make clear that 'impurity A' refers to an impurity of diclofenac sodium," Maj. Op. at 18. This does not comport with the presentation in Example 6, or with the US Pharmacopoeia identification of this impurity and this method of analysis. Patents are written for persons in the field of the invention. *See Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002) ("Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise for the generalist, instead of a concise statement for persons in the field.").

The majority further holds that the information in the US Pharmacopoeia cannot be considered when the claim is in the form "consisting essentially of." Maj. Op. at 16–19. However, knowledge in the field of the invention must always be considered. *See Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006) ("Claim definiteness is analyzed not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." (internal quotation marks omitted)).

The Court guided in *Nautilus*, 572 U.S. at 908, that "definiteness is to be evaluated from the perspective of someone skilled in the relevant art." *See also Energizer Holdings*, 435 F.3d at 1370 (claim definiteness is viewed as the claim would be understood by a person of ordinary skill in the field of the invention). The Actavis expert conceded that impurity A is a known degradation product of diclofenac sodium. Nonetheless, my colleagues hold that "Since 'impurity A' is indefinite, it logically follows that another

term, such as the 'degrades' term, which relies on 'impurity A' for its construction, must also be indefinite." Maj. Op. at 20. From this flawed premise the court holds: "[T]he 'favorable stability' property was indefinite which in this case, by extension, rendered the phrase 'consisting essentially of' indefinite." *Id.* at 8. "Indeed, if 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." *Id.* at 28. I repeat, there are no unlisted ingredients.

The majority illustrates this flaw in its holding in claim 19 of U.S. Patent No. 9,101,591, that includes both the term "consisting essentially of," Maj. Op. at 21 n.7, and the property "degrades [at] less than 1% over 6 months," *id.* at 20. The majority holds the claim invalid for indefiniteness although the advantageous property is actually stated in the claim.

The majority's conclusion is flawed, even on its erroneous premise that the basic and novel properties are required to be included in claims to compositions that are described in "consisting essentially of" form.

The majority's distinction between "consisting of" and "consisting essentially of" is unsupported in precedent

The panel majority holds that the consequence of claiming a composition as "consisting essentially of" the named ingredients, compared with "consisting of" the named ingredients, Maj. Op. at 33–34 n.8, is that the "consisting essentially of" claims are invalid for indefiniteness unless the claims include the "basic and novel properties" of the composition and how these properties are measured. This new rule is not in conformity with precedent. *See, e.g.*, *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349 (Fed. Cir. 2006), where this court explained that

"consisting of" permits "aspects unrelated to the invention." *Id.* at 1360.

The panel majority states that this meaning of "consisting of" is available only to "consisting essentially of," and that "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." Maj. Op. at 24, *op. cit.* The court in *Conoco* recognized the difference between "consisting of" and "consisting essentially of," stating that "while 'consisting of' limits the claimed invention, it does not limit aspects unrelated to the invention." 460 F.3d at 1360. However, no precedent has held that "consisting essentially of" composition claims are invalid unless they include the properties of the composition in the claims.

In the cases cited by the panel majority, Maj. Op. at 19, the properties of the novel compositions were recited in the specification or adduced in extrinsic evidence. In no case did the court hold that unless the properties were included in claims written as "consisting essentially of"" the claims are invalid. The majority's new ruling sows conflict and confusion.

This new rule of claiming compositions casts countless patents into uncertainty

The role of the claims is to state the subject matter for which patent rights are sought. *See In re Packard*, 751 F.3d 1307, 1313 (Fed. Cir. 2014) ("If the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." (quoting *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 258 F.2d 124, 136 (2d Cir. 1958))).

The usage "consisting essentially of" states the essential ingredients of the claimed composition. There are no

fuzzy concepts, no ambiguous usages in the listed ingredients. There is no issue in this case of the effect of other ingredients, as in *In re Hitachi Metals, Ltd.*, 603 F. App'x 976, 979 (Fed. Cir. 2015) ("[B]ecause the claims were drafted in the 'consisting essentially of' format, the scope of the claims can include those additional elements which do not materially affect the basic and novel characteristics of the claimed invention as specified in the '368 patent specification.").

Here no other components are asserted to be present, no "unnamed ingredients and steps." Even on my colleagues' flawed construction, the claims are not subject to invalidity for indefiniteness.

The requirement of clear and convincing evidence

Invalidity for indefiniteness must be established by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). This standard plainly is not met. "[A] claim is indefinite if its language might mean several different things and no informed and confident choice is available among the contending definitions." *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015) (internal quotation marks omitted). There was no evidence that persons of ordinary skill in the field of this invention would not understand the components of the composition claims with reasonable certainty.

Applying statute and precedent, the claims at issue have not been proved invalid for indefiniteness. From my colleagues' contrary ruling, I respectfully dissent.

III

INDUCEMENT TO INFRINGE

35 U.S.C. § 271(b) provides that "Whoever actively induces infringement of a patent shall be liable as an

infringer." The Actavis ANDA label instructs the method of use that is identical to the patented use. However, my colleagues hold that there can be no liability for induced infringement because some patients may not follow the label instructions. Thus the court holds that the provider of the product with instructions to use it in accordance with the infringing method cannot be liable for inducement to infringe.

To be sure, patients may not always comply with instructions. However, this does not insulate the provider from infringement liability. *See Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018) ("The contents of the label itself may permit the inference of specific intent to encourage, recommend, or promote infringement."). It is not disputed that the Actavis label "instructs users to perform the patented method." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

The summary judgment of non-infringement is incorrect in law. From my colleagues' contrary ruling on this aspect, I again respectfully dissent.