No. 20-___

In the Supreme Court of the United States

HZNP FINANCE LIMITED,
HORIZON THERAPEUTICS USA, INC.,

Petitioners,

v.

ACTAVIS LABORATORIES UT, INC.,

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the "basic and novel properties" identified in connection with a patent claim's transitional phrase "consisting essentially of" must independently satisfy the requirements of 35 U.S.C. § 112, ¶ 2, of the Patent Act, and the accompanying "reasonable certainty" standard set forth in *Nautilus, Inc. v. Biosig Instruments Inc.*, 134 S. Ct. 2120 (2014).

PARTIES TO THE PROCEEDING

Petitioners HZNP Finance Limited and Horizon Therapeutics USA, Inc. were Plaintiffs-Appellants below.

Respondent Actavis Laboratories UT, Inc. was Defendant-Cross-Appellant below.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioners HZNP Finance Limited and Horizon Therapeutics USA, Inc. are wholly owned subsidiaries of Horizon Therapeutics plc. Horizon Therapeutics plc has no parent corporation, and no publicly held company holds 10% or more of its stock.

RELATED PROCEEDINGS

HZNP Finance Limited, et al. v. Actavis Laboratories UT, Inc., No. 2017-2149 (the additional cases included in this consolidated appeal are: Nos. 2017-2152, -2153, -2202, -2203, -2206) (Fed. Cir. Oct. 10, 2019)

Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc., Civil Action No. 1:14-cv-07992-NLH-AMD (D.N.J.) (August 17, 2016 *Markman* Opinion)

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PETITION FOR A WRIT OF CERTIORARI

Petitioners HZNP Finance Limited and Horizon Therapeutics USA, Inc. respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS AND ORDERS BELOW

The opinion of the U.S. Court of Appeals for the Federal Circuit (Appx. 1-55) is reported at *HZNP Medicines LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019)

The order denying rehearing *en banc* (Appx. 95-101) is reported at *HZNP Fin. Ltd. v. Actavis Labs. UT, Inc.*, 950 F.3d 867 (Fed. Cir. 2020).

The district court's *Markman* opinion dated August 17, 2016 is unreported and reproduced at Appx. 58-85.

The district court's opinion on request for reconsideration dated January 6, 2017 is unreported and reproduced at Appx. 86-94.

STATEMENT OF JURISDICTION

The judgment of the U.S. Court of Appeals for the Federal Circuit was entered on October 10, 2019. Appx. 56-57. Horizon's petition for rehearing en banc was denied on February 25, 2020. Appx. 95-101. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1), and the Court's order dated March 19, 2020, extending the deadline to file petitions for writ of certiorari to 150 days from the date of the order denying a timely petition for rehearing.

STATUTORY PROVISIONS INVOLVED

Section 112, ¶ 2 of Title 35 of the United States Code[1] provides in relevant part:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[1] The applications resulting in the patents-in-suit were filed before the enactment of the Leahy-Smith America Invents Act ("AIA"). Accordingly, the pre-AIA version of 35 U.S.C. § 112 governs this case.

INTRODUCTION

The Federal Circuit's majority 8-4 decision creates a new rule of patent law that overturns decades of jurisprudence and finds no support in the language of 35 U.S.C. § 112, ¶ 2, of the Patent Act. Section 112, ¶ 2, on its face requires that the *claims* of a patent "particularly point[] out and distinctly claim[]" the invention. Despite this clear language, the Federal Circuit has issued a ruling whereby any patent claim reciting an invention using the transitional phrase "consisting essentially of" must be accompanied by a description of "basic and novel properties" in the patent specification, which must independently satisfy the definiteness requirement of 35 U.S.C. § 112, ¶ 2, even though such "basic and novel properties" are not themselves limitations of the patent claim. The Federal Circuit's decision must be reversed to avoid confusion regarding the validity of tens of thousands of validly issued patents containing patent claims employing the "consisting essentially of" transitional phrase, as well as countless patent applications currently under review by the United States Patent and Trademark Office ("PTO").[2]

At least four Federal Circuit judges have concluded that the majority's new rule is legally erroneous. For example, Judge Newman concluded in her opinion dissenting from the panel majority's decision that "[t]his new rule is not in conformity with precedent" and is "contrary to long-standing law and practice." Appx. 48; Appx. 52. Judge Newman reasoned that § 112 applies only to a patent's claims, and the

[2] Currently, the Manual of Patent Examining Procedure ("MPEP") does not provide any guidance for evaluating the scope or definiteness of the "basic and novel properties."

Federal Circuit's decision improperly "incorporated into the scope of the claims an evaluation of the basic and novel properties" which "is not the correct application of section 112(b)." Appx. 47-48.

Judge Lourie subsequently issued a dissenting opinion from the denial of Horizon's petition for en banc rehearing (denied 8 to 4), which was joined by Judge Newman, O'Malley, and Stoll. Appx. 97-101. These judges found the Federal Circuit's decision erroneous because "[t]he advantages of the invention, its utility and its basic and novel properties, are not in the claims" and "are not to be incorporated into claims for purposes of evaluating their indefiniteness" because "[i]t is the language of the claims that determines their definiteness" under § 112. Appx. 99. These judges further recognized that unrecited materials "may exist in an almost infinite variety" and thus "[i]n an infringement suit, the meaning of the 'consisting essentially of' language should boil down to a fact question, *i.e.*, whether the presence of an unrecited material in an accused product is in fact inconsistent with, or defeats the purpose of, the claimed composition." Appx. 100. These judges explained that "the fact that one generally has to determine this question at trial does not make the claim indefinite" and "[t]o hold to the contrary is to vitiate established usage that indefiniteness of claims is to be determined based on what the claim recites, not advantages cited in the specification." *Id.*

These judges further warned that the Federal Circuit's new rule would have practical implications far beyond the case at hand. Judge Newman characterized the decision as creating a "new rule" which "sows conflict and confusion" and "casts

countless patents into uncertainty." Appx. 53. Judge Lourie, joined by the others, agreed that "the issue is of broader importance" and cautioned that "under the rule this opinion purports to adopt, any uncertainty concerning advantages, utility, or methods of determining such could, wrongly in my view, be translated into indefiniteness of claims." Appx. 99; Appx. 101.

The implications of the Federal Circuit's 8-4 majority decision are significant. As one commentator put it, "the implications of this decision are wide and unsettling" because over 32,000 U.S. patents have been granted over the past 20 years using the phrase "consisting essentially of" and moving forward the "basic and novel characteristics of the claimed invention will now become a major point of contention during the claim construction phase and beyond." Aydin Harston & Alvin Lee, *Time to Rethink "Consisting Essentially of" as a Claim Limitation*, Biologics & Biosimilars (Nov. 11, 2019). Indeed, according to the PTO's database, over 42,000 patents have issued using this transitional phrase since 2000.[3] According to Harston and Lee, patents directed to peptide and antibody inventions are particularly at risk.

This Court can immediately resolve the question of whether the definiteness requirement of 35 U.S.C. § 112, ¶ 2, applies to the "basic and novel properties" of an invention claimed using the phrase "consisting essentially of," as there are no factual or additional legal issues to complicate this Court's analysis. This Court should grant

[3] Based on PTO Patent Full-Text and Image Database searches (http://patft.uspto.gov/netahtml/PTO/search-adv.htm) conducted on July 23, 2020 using the query: ACLM/("consisting essentially" or "consists essentially" or "consist essentially") andnot ("group consisting essentially" or "group consists essentially" or "group consist essentially") and ISD/1/1/2000->7/23/2020.

review to correct the Federal Circuit's mistake and reaffirm that 35 U.S.C. § 112, ¶ 2 applies only to the claims of the patent, not the "basic and novel properties" of the invention.

STATEMENT OF THE CASE

I. Legal Standard

The definiteness requirement of 35 U.S.C. § 112, ¶ 2, provides that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." In *Nautilus*, the Supreme Court replaced the prior "insolubly ambiguous" standard for definiteness, and 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." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). The *Nautilus* decision did not discuss or relate to the transitional phrase "consisting essentially of."

Prior to this case, no court had ever applied the definiteness requirement of 35 U.S.C. § 112, ¶ 2, to the "basic and novel properties" identified from a patent specification in connection with the term "consisting essentially of." Rather, the transitional phrase "consisting essentially of" has consistently been treated as a legal term of art in patent law which is "understood to permit 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 Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239

(Fed. Cir. 2003); *see also PPG Indus. v. Guardian Indus. Corp*., 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Nothing in the *Nautilus* decision compels or sanctions the Federal Circuit's departure from this long-established precedent.

II. The Claimed Invention

This case involves U.S. Patent No. 8,252,838 ("the '838 patent") and related family members which are directed to topical diclofenac sodium gel formulations for use in treating osteoarthritis. In several instances, the inventors of the '838 patent elected to claim their improved formulation using the "consisting essentially of" transitional phrase. Appx. 20-21. Claim 49 of the '838 patent is illustrative and 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.

Appx. 21. The patent specification describes that the inventive formulations have certain advantages over the prior art topical diclofenac sodium liquid formulation, including (i) better drying time, (ii) higher viscosity, (iii) increased transdermal flux, (iv) greater pharmacokinetic absorption *in vivo*, and (v) favorable stability. Appx. 23.

III. District Court Proceedings

The District Court first recognized that "consisting essentially of" is a transitional phase having a well-established legal meaning: it requires that the invention necessarily includes the listed ingredients and is open to the inclusion of additional unlisted ingredients "that do not materially affect the basic and novel properties of the invention." Appx. 71-72 (*citing PPG Indus.*, 156 F.3d at 1354). Because the "basic and novel properties" of the invention were in dispute, the District Court concluded it was necessary to identify the "basic and novel properties" so as "to delineate what must be shown for the purposes of infringement or invalidity." Appx. 72.

The District Court found the "basic and novel properties" of the invention were set forth in the '838 patent and identified them as: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. Appx. 80.

However, even though no court had ever applied the definiteness requirement of 35 U.S.C. § 112, ¶ 2 to "basic and novel properties," the District Court assessed the definiteness of each "basic and novel property," citing the Supreme Court's "reasonable certainty" standard in *Nautilus*. In doing so, the District Court found that the basic and novel properties "better drying time" and "favorable stability" were indefinite because the specification described more than one way of measuring these parameters. Appx. 81-84; Appx. 91-94. Notably, no unlisted ingredients were at issue before the District Court.

IV. Federal Circuit Proceedings

On appeal, the Federal Circuit affirmed the District Court's identification of the five basic and novel properties of the invention: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. Appx. 23. Regarding whether the *Nautilus* definiteness standard applied to the basic and novel properties, the Federal Circuit reasoned that "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." Appx. 28. The Federal Circuit concluded that "[t]o 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." Appx. 28. The Federal Circuit found the District Court did not err in determining that the basic and novel property of "better drying time" was indefinite, because the specification described two methods of measuring drying time, which the District Court found provided inconsistent results at inconsistent times. Appx. 29-33.

Judge Newman issued an opinion concurring in part and dissenting in part. Judge Newman dissented with respect to the panel majority's analysis of the "basic and novel properties" and the finding that "consisting essentially of" was indefinite. Appx. 47-54.

Horizon filed a petition for rehearing en banc which the Federal Circuit denied (8 to 4) on February 25, 2020. Appx. 96. Judge Lourie issued the dissenting opinion, joined by Judges Newman, O'Malley, and Stoll, in which they concluded the Federal

Circuit's decision was erroneous and would have implications beyond the case at hand. Appx. 97-101.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Construction of "Consisting Essentially of" Vitiates Seventy Years of Established Usage

As Judge Lourie explained in his 8-4 dissent, the term "consisting essentially of" is "clear, definite, language." Appx. 100. Indeed, for seven decades, as described in detail below, the PTO, the Court of Customs and Patent Appeals (C.C.P.A.) and the Federal Circuit consistently understood the phrase "consisting essentially of" to be a term of art with a *definite* legal definition. Accordingly, the Federal Circuit majority's 8-4 decision finding "consisting essentially of" indefinite based on uncertainty regarding one of the "basic and novel properties," which are not elements of the patent claims, improperly "vitiate[s] established usage that indefiniteness of claims is to be determined based on what the claim recites, not advantages cited in the specification." Appx. 100.

The history of the phrase "consisting essentially of" began in 1948 when the phrase was first construed when an applicant appealed the PTO's final rejection of a patent claim to a tape having an adhesive composition "consisting essentially of" three components over a prior art composition that had the same three components plus an additional fourth component. *Ex parte Davis*, 80 U.S.P.Q. 448, 448-49 (Pat. Office Bd. App. 1948). The PTO Examiner rejected the claims to the tape because "the expression 'consisting essentially of' … [was] not considered as definitely precluding the presence of ingredients other than those recited." *Id.* at 449. The PTO Board of

Appeals initially agreed that the phrase was "self-contradictory, and render[ed] the claims indefinite," but then modified its decision to adopt a "code of terms for use in compositions to aid uniformity of practice" used by a group of Primary Examiners at the PTO, whereby recital of "essentially" along with "consisting of" was construed as "rendering the claim open only for the inclusion of unspecified ingredients which do not materially affect the ***basic and novel characteristics*** of the composition." *Id.* at 449-450 (emphasis added). Having adopted this construction, the Board then analyzed whether the fourth component present in the prior art "materially change[d] the fundamental character of the three-ingredient composition" such that the claims were patentably distinct. *Id.* at 450.

The C.C.P.A soon thereafter adopted the PTO Board's construction of "consisting essentially of" and the use of "basic and novel properties" as a tool to determine whether additional unrecited elements materially affected the invention such that a composition containing the unrecited elements was excluded from the claimed scope. *See, e.g.*, *In re Janakirama-Rao*, 317 F.2d 951, 952-54 (C.C.P.A. 1963); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969); *In re Herz*, 537 F.2d 549, 552-53 (C.C.P.A. 1976). When the intrinsic record failed to identify "basic and novel properties," the C.C.P.A. held that the patentee failed to provide evidence that the claimed invention was patentably distinct from the prior art. *See In re Janakirama-Rao*, 317 F.2d at 954.

Importantly, neither the PTO Board nor the C.C.P.A. viewed identification of the "basic and novel properties" as a necessary part of claim construction to determine

the scope of "consisting essentially of," or considered the phrase "consisting essentially of" indefinite if the "basic and novel properties" were undefined.

Until this case on appeal, the Federal Circuit adhered to the C.C.P.A. precedent. The Federal Circuit construed "consisting essentially of" as limiting the claim scope to the specific listed ingredients and excluding any additional ingredients that materially affected the "basic and novel properties." *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984); *PPG Indus.*, 156 F.3d at 1354-55; *AK Steel*, 344 F.3d at 1239-40. And the Federal Circuit assessed the "basic and novel properties" *only when needed* as part of the fact-based inquiry to determine whether additional unrecited elements in an accused product or prior art product made a material difference. *PPG Indus.*, 156 F.3d at 1354-55; *AK Steel*, 344 F.3d at 1239-40.

To be sure, the Federal Circuit recognized that the claim phrase "consisting essentially of" inherently contains some imprecision. *PPG Indus.* 156 F.3d at 1355 (recognizing that "consisting essentially of" claims are not precise or specific); *see also AK Steel*, 344 F.3d at 1239 ("In view of the ambiguous nature of the phrase, it has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'"). But, consistent with the C.C.P.A. precedent, the Federal Circuit instructed that it was the purview of the trier of fact to resolve any such imprecision because the application of "basic and novel properties" is a factual question. *PPG Indus.* 156 F.3d at 1355 (warning that a court may not, through claim construction,

give a "consisting essentially of" claim "whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product" because that task is for the finder of fact).

Importantly, the Federal Circuit never, prior to this case on appeal, held that the phrase "consisting essentially of" is invalid under 35 U.S.C. § 112, ¶ 2 because of its inherent imprecision. And the Federal Circuit never held that the "basic and novel properties" must be identified in order to determine the metes and bounds of "consisting essentially of," or treated the "basic and novel properties" as claim limitations that are subject to the requirements of 35 U.S.C. § 112, ¶ 2.

In this case, the Federal Circuit's 8-4 majority deviates from decades-old established construction of "consisting essentially of." The majority articulates a new standard, which requires identification of "basic and novel properties" for the purposes of evaluating them under the definiteness standard as if they were claim limitations. This was legal error.

II. The Federal Circuit Majority's New Rule Subjecting "Basic and Novel Properties" to the Definiteness Standard Is Without Legal Basis

On its face, the definiteness requirement of 35 U.S.C. § 112, ¶ 2 is strictly limited to the claims. Accordingly, as Judge Lourie explained in his 8-4 dissent, "it is the language of the claims that must not be indefinite, not the understanding or clarity of an advantage of the invention. The advantages of the invention, its utility and its basic and novel properties, are not in the claims." Appx. 99.

Prior to its 8-4 decision, the Federal Circuit repeatedly observed, "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). "We look to the words of the claims themselves ... to define the scope of the patented invention." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir 1996). "The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc). Nothing in the law justifies the Federal Circuit majority's deviation from this bedrock principle.

The Federal Circuit panel majority relied, in part, on this Court's decision in *Nautilus*. But *Nautilus* had nothing to do with the interpretation of "consisting essentially of." Nothing in that decision contemplates overturning decades of precedent establishing "consisting essentially of" as a term of art or transforms the "basic and novel properties" into claim elements that must be construed and evaluated against the definiteness standard of 35 U.S.C. § 112, ¶ 2. *Nautilus* merely clarifies the indefiniteness standard for ***claim terms*** stating, "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." 134 S. Ct. at 2124 (emphasis added).

The Federal Circuit panel majority's reliance on *PPG Indus.* and *AK Steel* as providing alleged "crucial teachings" which justify extension of 35 U.S.C. § 112, ¶ 2,

to the "basic and novel properties" of the invention is equally misplaced. (Appx. 28.) But, again, neither *PPG Indus.* nor *AK Steel* involves analysis of the ***definiteness*** of "consisting essentially of" or of the "basic and novel properties" identified in connection with that claim phrase. Neither case compels or sanctions reading "basic and novel properties" of an invention into the claims or subjecting them to the requirements of 35 U.S.C. § 112, ¶ 2. To the contrary, these decisions illustrate the Federal Circuit's consistent holding that any imprecision associated with the claim phrase "consisting essentially of" is to be resolved by a fact-finder. *See PPG Indus.* 156 F.3d at 1355; *AK Steel*, 344 F.3d at 1239.

III. The Notice Function of "Consisting Essentially of" Claims Is Served Without Need for Incorporation of the "Basic and Novel Properties"

The Federal Circuit panel majority's assertion that, under the *Nautilus* standard, the "basic and novel properties" of the invention must be described with "objective boundaries" to give the public "clear notice" of the claim's scope is unfounded. Appx. 25-26. The Federal Circuit has always held that any uncertainty associated with the phrase "consisting essentially of" can and *should* be resolved by the fact-finder by assessing whether the unrecited ingredients materially affect the "basic and novel properties" of the claimed composition. *PPG Indus.* 156 F.3d at 1355. In this regard, Judge Lourie correctly explains in his 8-4 dissent that "the fact that one generally has to determine this question at trial does not make the claim indefinite." Appx. 100.

In this case, the claims at issue clearly identified the ingredients that are required in the invention. As Judge Newman recognized in panel dissent, it is "hard

to imagine a clearer statement than a list of the ingredients that the claimed formulation 'consists essentially of.'" Appx. 48. The list of claimed ingredients combined with the clear identification of five "basic and novel properties" is all that is required to provide the public with notice as to the scope of the invention. This information informs a person of ordinary skill in the art ("POSA"), and the public, that the claims cover only those compositions which contain all of the listed ingredients and which, to the extent additional unrecited ingredients are present, have largely equivalent properties for each of the five identified properties. A POSA and the public are therefore on notice that they can avoid infringement so long as they omit one of the required ingredients or include an additional ingredient that materially affects at least one of the five properties. As is always the case in a patent infringement case, the sufficiency of noninfringement evidence is to be decided by the trier of fact. *PPG Indus.* 156 F.3d at 1355.

IV. The Federal Circuit's New Rule Casts a Pall of Uncertainty Over the Validity of Issued Patents and Future Applications Submitted to the Patent Office

The Federal Circuit's decision, if not reversed, will have long ranging and negative consequences for the PTO and the nation's court system. As Judge Newman rightly warned in her panel dissent, the Federal Circuit's decision creates a "new rule of claiming compositions" which "casts countless patents into uncertainty." Appx. 53. And as Judge Lourie echoed in his 8-4 dissent, this "issue is of broader importance" because "the principle of importing an uncertainty in measuring an advantage of an

invention could have unintended potential effects well beyond this particular case." Appx. 99; Appx. 101.

One such negative impact will be felt by inventors. The purpose of identifying the "basic and novel properties" is to assess the impact of *future*, but *not yet identified*, ingredients that are added to the claimed listing of ingredients (either in a prior art description or in a future composition prepared by a potential infringer). Because these future assessments cannot be known to an inventor, the inventor cannot possibly envision the "bounds" of every test that might be used to carry out this assessment. In this regard, Judge Lourie correctly recognized that the potential unrecited materials "may exist in an almost infinite variety" and "until a suit arises, one does not know what such an inconsistent material might be." Appx. 100. Importantly, the use of different ingredients may require testing according to different methodologies. It is unduly burdensome to require the patentee to design and describe in the patent specification how to measure each of the infinite potential unrecited ingredients that could be added and set forth precisely the metes and bounds of what effect is considered material. Such an extensive notice requirement would be very difficult, if not impossible, for the patentee to meet. It is improper to place this burden on the patentee who is not necessarily in the best position to predict every change or improvement another might make. So long as the identity of the basic and novel property can be determined, the sufficiency of infringement evidence should be evaluated by the trier of fact, as has always been the case.

Moreover, to find a patentee's claim invalid simply because the patentee has failed to recite a test *in the patent specification* to determine the effect of any potential unrecited ingredient that someone might add is fundamentally unfair. Under the Federal Circuit's new rule, even in the case of a readily discernable answer to the factual question of whether a specific unrecited ingredient at issue materially affects the "basic and novel properties," the claim could still be argued to be indefinite simply because the POSA could not discern the full scope of every potential fact pattern and test implicated by the "basic and novel properties." This should not be the law.

The PTO will also experience the negative impact of this new rule. The Federal Circuit's decision, if allowed to stand, will alter how the PTO will need to evaluate patent applications. As Judge Lourie recognized, the utility or advantage of the claimed compound are not currently challenged in examination unless they are not credible. Appx. 101 (citing MPEP § 2107 (9th ed. Rev. 08.2017, Jan. 2018)). Indeed, the Manual of Patent Examining Procedure ("MPEP") currently does not provide any guidance for evaluating the scope or definiteness of the "basic and novel properties." Moving forward, for every "consisting essentially of" claim, the PTO will need to evaluate each "basic and novel property" independently to determine if it contains "objective boundaries" necessary to satisfy the *Nautilus* standard. This will unduly complicate patent prosecution and burden the PTO.

Finally, the court system will be negatively impacted by this new rule. The district court's decision, affirmed by the Federal Circuit, has facilitated, and will continue to facilitate, meritless indefiniteness challenges to "consisting essentially of" claims, even in the absence of any unlisted ingredients at issue, and significantly

complicating how courts analyze "consisting essentially of" cases at the claim construction phase. *See Prostrakan, Inc. v. Actavis Labs. UT, Inc.*, Civ. No. 16-cv-0044, 2017 WL 3028876, at *8-9 (E.D. Tex. July 15, 2017); *Mayne Pharma Int'l Pty Ltd. v. Merck & Co., Inc.*, Civ. No. 15-438, 2016 WL 7441069 (D. Del. Dec. 27, 2016). Previously, courts would at most construe "consisting essentially of" according to its well-established legal meaning and stop, without identifying the "basic and novel properties" unless there is some dispute as to the identity of the basic and novel properties. *See, e.g.*, *Depomed, Inc. v. Sun Pharma Global FZE,* C.A. No. 11-3553 (JAP), 2012 WL 3201962, at *13 (D.N.J. Aug. 3, 2012); *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, 162 F.Supp.3d 405, 420-21 (D.N.J. Nov. 18, 2015). Under the panel's decision, this practice is effectively over. As Judge Newman's panel dissent recognizes, it no longer matters whether any unlisted ingredients are even in dispute. Appx. 48; Appx. 52; Appx. 54.) Moving forward, in every instance, courts will have to identify the "basic and novel properties" and determine whether they have "objective boundaries."

In sum, the Federal Circuit's decision will have a significant negative effect on patent prosecution at the PTO and patent litigation in district courts and the Federal Circuit. The Court should address this issue now, before more cases are erroneously decided under the Federal Circuit's new rule.

CONCLUSION

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

Respectfully submitted,

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APPENDIX A

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.

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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—

[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.

[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 25° 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.

APPENDIX B

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. 1:15-cv-07742-NLH-AMD, 1:16-cv-00645-NLH-AMD, 1:14-cv-07992-NLH-AMD, 1:15-cv-05025-NLH-AMD, 1:15-cv-06131-NLH-AMD, 1:15-cv-06989-NLH-AMD, Judge Noel Lawrence Hillman.

JUDGMENT

THIS CAUSE having been considered, it is

ORDERED AND ADJUDGED:

AFFIRMED

ENTERED BY ORDER OF THE COURT

October 10, 2019

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

APPENDIX C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND LIMITED, et al., Plaintiffs, v. ACTAVIS LABORATORIES, UT, INC., et al., Defendants.	Civil No. 14-7992 (NLH/AMD) **OPINION**

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HILLMAN, District Judge

Presently before the Court in this Hatch-Waxman Act[1] action is the dispute over the construction of claims in nine patents relating to PENNSAID® 2%, which is the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of the pain of osteoarthritis ("OA") of the knees. Plaintiff Horizon (Horizon Pharma Ireland Limited, HZNP Limited and

[1] The Third Circuit Court of Appeals recently explained,

> With the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, Congress attempted to balance the goal of "mak[ing] available more low cost generic drugs," H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48, with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement, see H.R.Rep. No. 98-857, pt. 2, at 30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2714. The Act seeks to accomplish this purpose, in part, by encouraging "manufacturers of generic drugs . . . to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices." S. Rep. No. 107-167, at 4 (2002).

King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 394 (3d Cir. 2015).

Horizon Pharma USA, Inc.) is the current owner and assignee of the patents-in-issue, and of the PENNSAID® 2% New Drug Application ("NDA"); all rights therein were acquired from third parties. These patents are: U.S. Patent Nos. 8,252,838 ("the '838 patent"), 8,563,613 ("the '613 patent"), 8,871,809 ("the '809 patent"), 9,066,913 ("the '913 patent"), 9,101,591 ("the '591 patent"), 8,546,450 ("the '450 patent"), 8,217,078 ("the '078 patent"), 8,618,164 ("the '164 patent") and 9,132,110 ("the '110 patent").

The patents may be segregated into groups in accordance with their related specifications. The first group of Horizon patents - the '838, '613, '809, '913 and '591 patents - share substantially identical specifications and claim priority to the same provisional application filed on October 17, 2006. According to Horizon, the inventors recognized a significant unmet need for, *inter alia*, topical OA pain treatments suitable for chronic use that will deliver the active agent to the underlying tissue in sufficient concentration. The second group of Horizon patents - the '450, '078, '164 and '110 patents - also share substantially identical specifications, and claim priority to the same provisional application filed on October 31, 2012. Horizon states that the inventors recognized a need for, *inter alia*, improved methods of dosing topical diclofenac formulations.

Horizon has filed several Hatch-Waxman actions alleging patent infringement against generic companies seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents. This particular action concerns claim construction issues relevant to Actavis Laboratories UT, Inc. ("Actavis"). Horizon brought this action in response to Actavis' assertion that the generic copy of PENNSAID® 2% described in Actavis' Abbreviated New Drug Application No. 207238 ("ANDA"), if approved by the FDA, would not infringe any valid and enforceable patent owned by Horizon.[2]

A claim construction hearing was held on March 3, 2016. Following the conclusion of the parties' arguments, the Court directed the parties to submit supplemental briefing, and on June 7, 2016, the Court, having considered the entire record and additional briefing and argument by counsel, issued an oral Opinion on the Court's final construction of the patent claims. This Opinion formally memorializes the Court's findings as to its construction of the patent claims at issue pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

[2] This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271.

I. LAW OF CLAIM CONSTRUCTION

Claim construction is "an issue for the judge, not the jury." Markman v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996); see also Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015) ("This ultimate interpretation is a legal conclusion."). "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art [the "POSA"] in question at the time of the invention." Id. at 1313. Claim construction begins with the intrinsic evidence of the patent -- the claims, the specification, and the prosecution history -- and may require consultation of extrinsic evidence to understand the state of the art during the relevant time period. Teva Pharms., 135 S. Ct. at 841.

As part of construing claims, the Court can assess whether a claim term is indefinite, and reach "'a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims.'" In re Aoyama, 656 F.3d 1293, 1299 (Fed. Cir. 2011) (quoting Personalized Media Commc'ns, L.L.C. v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998)). For a

claim term to be definite under 35 U.S.C. § 112, ¶ 2 (2012),[3] "a patent's claims, viewed in the light of the specification and prosecution history, [must] inform those skilled in the art about the scope of the invention with reasonable certainty." Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2129 (2014).

It is permissible to read in testing conditions from the specification without violating the basic canon of construction not to import limitations from the specification into the claims, but only where this will "reconcile[ ] the ambiguous claim language with the inventor's disclosure." Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1378–79 (Fed. Cir. 2005). Where, however, the specification discloses multiple methods for evaluating a claim limitation without guidance to a person of ordinary skill in the art about which method to use, the claim limitation is indefinite. Dow Chem. Co. v. Nova Chems. Corp. (Can.), 803 F.3d 620, 634–35 (Fed. Cir. 2015); Teva Pharms. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1344–45 (Fed. Cir. 2015), on remand from 135 S. Ct. 831 (2015).

[3] The statute has been subsequently amended under the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011), such that this provision has been replaced by 35 U.S.C. § 112(b). Because the applications predate the AIA, the pre-AIA version of § 112 applies. Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374, 1377 n.1 (Fed. Cir. 2015), on remand from 134 S. Ct. 2120 (2014).

II. DISPUTED TERMS

As set forth above, there are nine patents asserted in this matter. Of these, five patents - U.S. Patent Nos. 8,252,838; 8,563,613; 8,871,809; 9,066,913; and 9,101,591 - are part of the "'838 Patent Family" and all agreed to have the same specification. The other four patents - U.S. Patent Nos. 8,546,450; 8,217,078; 8,618,164; and 9,132,110 - are part of the "'450 Patent Family" and similarly agreed to have the same specification.

All of the disputed terms for the Court to construe are contained within the '838 Patent Family, thus all references to the specification will be to the specification of the '838 Patent.

A. "the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity"

Horizon's Proposed Construction	**Defendants' Proposed Construction**
Less than 0.1% 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	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If impurity A is construed to mean USP Diclofenac Related Compound A RS, then the remainder of the term should be given its plain and ordinary meaning.

Court's construction: indefinite as to the identity of "impurity A"

Horizon's construction seeks to equate the claim term "impurity A" with USP Diclofenac Related Compound A RS ("USP Compound A").[4] Horizon acknowledges that no reference to USP Compound A exists in the intrinsic evidence, but relies on the fact that a POSA would know that "impurity A" would refer to USP Compound A. Actavis submits that the language of the specification and absence of testing information within the specification make the identity of "impurity A" impossible to know. Actavis also argues that even if "impurity A" is knowable, the verb "produces" mandates an assessment of the amount of "impurity A" before storage to determine a baseline amount to compare against the amount of "impurity A" after the six month storage period to calculate what was "produced" during the storage period, as opposed to what was present as a result of the synthesis of diclofenac sodium.

Looking to the specification, as mentioned, USP Compound A is never mentioned. Horizon's position is that because the relevant pharmacopoeias at the time -- the U.S. Pharmacopoeia ("USP"), the European Pharmacopoeia ("Ph. Eur."), and the

[4] The chemical name for this compound is either *N*-(2,6-dichlorophenyl)indolin-2-one (see USP (26th ed. 2003) at 1975 (Pl.'s Ex. 16); USP (24th ed. 2000) at 1786 (Pl.'s Ex. 17)) or 1-(2,6-dichlorophenyl)-1,3-dihydro-2*H*-indol-2-one (see Ph. Eur. (5th ed. 2004) at 1420 (Pl.'s Ex. 18); Ph. Eur. (6th ed. 2005) at 1687 (Pl.'s Ex. 19)). The literature references referred to by both experts refer to USP Compound A by both names.

British Pharmacopoeia ("BP") -- identify five degradants for sodium diclofenac by letters (e.g., A, B, C), a POSA would know that "impurity A" meant the first impurity for sodium diclofenac, which is disclosed in the USP as USP Compound A. Actavis does not appear to disagree that this is a possibility, but it argues that without any further identifying information given about "impurity A," it would be impossible for a POSA to know what "impurity A" is.

The only identity information provided for "impurity A" in the specification are retention times derived from a high performance liquid chromatography ("HPLC") characterization. However, the specification merely says "the samples were tested for impurities by high performance liquid chromatography (HPLC)." '838 Patent at 23:50-52. The specification provides no additional information about the conditions under which the HPLC experiment were undertaken -- most notably, details regarding the column, the mobile phase, and the flow rate are not given. (See Marvin C. McMaster, HPLC: A Practical User's Guide 53-56 (2d ed. 2007).)

Actavis' expert explains that the disclosure is insufficient for a POSA to replicate and understand the HPLC results to identify "impurity A." (Michniak-Kohn Decl. ¶¶ 52-54.) Dr. Kohn also explains that the specification fails to inform a POSA whether "impurity A" is produced as a result of

the diclofenac, or as a result of any of the other excipients in the formulation. (Id. ¶ 51.) Horizon's expert responds that the literature available at the time would demonstrate that "impurity A" was USP Compound A. (Walters Resp. Decl. ¶ 16–20.)

Dr. Walters assumes that the HPLC experiment was carried out using a pharmacopoeia chromatographic system (see Walters Resp. Decl. ¶ 16), but the specification does not support this position. The word "pharmacopoeia" appears nowhere in the '838 Patent, and Dr. Walters has not explained why a POSA would know that the HPLC tests described in the '838 Patent were undertaken using a pharmacopoeia chromatographic system. Looking to the pharmacopoeia excerpts submitting by Horizon, they do not comport with the HPLC characterization data disclosed in the specification. Both editions of the Ph. Eur. and the USP provide detailed descriptions of a reference solution, the mobile phase, the flow rate, and details about the column. (See Ph. Eur. (6th ed. 2005) at 1686–87; Ph. Eur. (5th ed. 2004) at 1421; USP (26th ed. 2003) at 595–96; USP (24th ed. 2000) at 546.) Further, even assuming that the HPLC experiment in the '838 Patent was undertaken using pharmacopoeia chromatographic systems, the relative retention times disclosed in the specification only comport with the characterization of diclofenac given in the USP (0.6 for USP Compound A and 1.0 for

diclofenac),[5] and do not comport with the information given in the Ph. Eur. (0.48 for USP Compound A and 1.0 for diclofenac).[6] The specification provides no guidance as to which of the proposed pharmacopoeia chromatographic systems a POSA could use to evaluate the identity of "impurity A."

Further, in neither of the literature references relied upon by Dr. Walters that he asserts use pharmacopoeia chromatographic systems does the reference omit the details of the HPLC experiment (see Roy (2001) at ACT-PENN0014822 (explicitly relying on the BP for the HPLC conditions while still explaining in detail the conditions used); Hajkova (2002) at HZNPENN_00071424 (explicitly relying on the USP for baseline HPLC conditions while also disclosing conditions for a newly described HPLC experimental setup)) or identify USP Compound A by anything other than its actual chemical formula and/or structure (see Roy (2001) at ACT-PENN0014821 ("a stable intermediate, 1-(2,6-dichlorophenyl)indolin-2-one, which is commonly known as the indolinone derivative"); Hajkova (2002) at

[5] This corresponds to 6.6 minutes for "impurity A" and 11 minutes for diclofenac as disclosed in the specification.

[6] This would correspond to either an elution of "impurity A" at 5.28 minutes if diclofenac eluted at 11 minutes as disclosed, or an elution of diclofenac at 13.75 minutes if "impurity A" eluted at 6.6 minutes as disclosed.

HZNPENN_00071423 ("The main impurity, 1-(2,6-dichorophenyl)indolin-2-one (DPI, Fig. 1) . . . .")).

The identity of "impurity A" as claimed in claim 4 of the '913 Patent is unknowable to a reasonable certainty to a POSA. Accordingly, "impurity A" is indefinite. The Court need not reach the issue of whether "produces" requires an assessment of the amount if "impurity A" before storage to provide a baseline to compare against the amount of "impurity A" after the six month storage period.

B. "the formulation degrades by less than 1% over 6 months"

Horizon's Proposed Construction	**Defendants' Proposed Construction**
Less 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	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, the term should be given its plain and ordinary meaning.

Court's construction: indefinite

Horizon seeks to do two things in their construction: (1) explain storage conditions by relying on Example 6 of the specification; and (2) explain what it means if something "degrades" by using "impurity A" from Example 6. Actavis responds that this is improper importation of limitations from the specification into the claims, and that even if this were permissible, the specification provides multiple methods of

storage without specifying when one is proper, making the terms indefinite.

Having already concluded that the identity of "impurity A" is indefinite, this term must also be indefinite. No other explanation for how to identify the means of degradation is provided. Even if the Court were to try to identify another way to evaluate degradation, the specification does not provide guidance. The specification refers to stability and degradation as two sides of the same coin, a point which Horizon also made during the hearing. (See Hr'g Tr. at 45:22–46:1.) However, stability is referred to as a catch all for a number of things, especially in Example 3 when the gels "remain stable for at least six months demonstrating: no phase separation, negligible shift in pH, and low amounts of degradation products (<0.04%)." '838 Patent at 16:39–41; see also id. at 12:56–58 (referring to discoloration and phase separation in the context of stability), 20:37–64 (referring to appearance for stability), 23:30–24:32 (referring to production of "impurity A" for stability). For purposes of claim construction, it is presumed that claim terms are used consistently throughout a patent. Phillips, 415 F.3d at 1314. Thus, it is unclear when "stability" and therefore "degradation" is referring to production of "impurity A," or something else, such as appearance, phase separation, and/or pH shift.

Thus, no matter how the Court tries to interpret the term, the result is indefiniteness. Either degradation is equated with "impurity A", which has already been deemed indefinite, or the Court is presented with multiple methods for how to evaluate stability -- and accordingly how to evaluate degradation -- without further guidance, rendering the term indefinite.

The Court need not reach the issue of whether Horizon's proposed construction would impermissibly import limitations from the specification with respect to storage conditions.

C. "consisting essentially of"

Horizon's Proposed Construction	**Defendants' Proposed Construction**
Legal issue – no construction needed in Markman phase; also, meaning cannot be ascertained in the absence of proper context	Comprising; if interpreted otherwise, the claims are invalid as indefinite and/or lacking adequate written description under 35 U.S.C. § 112

Court's construction: indefinite due to indefiniteness of the basic and novel properties of the invention

1. "Consisting Essentially Of" and the "Basic and Novel Properties" Require Construction

"Consisting essentially of" is a transitional phrase that has a well-established legal meaning in Federal Circuit case law. "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the

invention." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). This presents a middle ground between the open-ended "comprising" that does not exclude any unrecited claim elements and the closed "consisting of" that excludes any elements not explicitly recited in the claim. AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

When asked to construe this term, courts have generally declined to construe the term, or declined to provide any further construction beyond the well-established legal meaning of the term. See, e.g., Depomed, Inc. v. Sun Pharma Global FZE, Civ. No. 11-3553 (JAP), 2012 WL 3201692, at *13 (D.N.J. Aug. 3, 2012); Biovail Labs. Int'l SRL v. Abrika, LLLP, No. 04-61704, 2006 WL 6111777, at * 18 (S.D. Fla. Aug. 24, 2006); Classified Cosmetics, Inc. v. Del Labs., Inc., No. 03-4818, 2004 WL 5645578, at *5 (C.D. Cal. June 14, 2004).

When, however, the "basic and novel properties" themselves are in dispute, courts have construed the term in order to define the "basic and novel properties" to delineate what must be shown for the purposes of infringement or invalidity. See, e.g., AK Steel, 344 F.3d at 1239-40 (determining the basic and novel property of the invention by referring to the specification); L'Oreal S.A. v. Johnson & Johnson Consumer Cos., Inc., No. 12-98-GMS, Docket Item 183, slip op. at 1 n.2 (D. Del. Nov. 5, 2014) ("As with claim construction, the court determines

the basic and novel properties of an invention as a matter of law, while resorting to the same sources of evidence used for claim construction."); Trs. of Boston Univ. v. Everlight Elecs. Co., Ltd., 23 F. Supp. 3d 50, 63-65 (D. Mass. 2014) (noting that "[t]he caselaw is somewhat unclear as to how to determine the 'basic and novel properties' of an invention" and that "[t]his is a turgid, difficult nook of patent law"); Momentus Golf, Inc. v. Swingrite Golf Corp., 312 F. Supp. 2d 1134, 1144 (S.D. Iowa 2004) (identifying "[t]he novel property" of the claimed invention in construing "consisting essentially of"), rev'd, 187 F. App'x 981 (Fed. Cir. 2006) (reversing judgment of noninfringement for misconstruing what would materially alter the basic and novel property); Kim v. Conagra Foods, Inc., No. 01-2467, 2003 WL 2122266, at *8 (N.D. Ill. May 23, 2003) (identifying "the novel property of the claimed invention" in discussing claim construction); General Elec. Co. v. Hoechst Celanese Corp., 698 F. Supp. 1181, 1187 (D. Del. 1988) (holding that "the determination of the basic and novel characteristic of [the asserted patent] is part of determining the scope of the claim" and then declining to do so due to a disputed issue of fact under pre-Markman case law). It further appears that where the parties can agree on the basic and novel properties, then the issue of what materially affects those properties is not raised until the infringement and invalidity analyses. See,

e.g., PPG Indus., 156 F.3d at 1354 ("[The parties] agreed that the basic and novel characteristics of the glass are color, composition, and light transmittance.").

Based on the weight of authority, the Court will construe "consisting essentially of" in accordance with the well-established legal meaning, "consisting of only the specified materials and those that do not materially affect the basic and novel properties of the claimed invention." Because the parties dispute what those basic and novel properties or characteristics are, the Court will go on to identify them.[7]

2. Nautilus Applies to the "Basic and Novel Properties"

A major dispute between the parties is whether the Nautilus standard applies to the determination of the "basic and novel properties." The parties agree that no court has yet to apply the Nautilus standard for indefiniteness to this issue, and the Court has been unable to identify any. Accordingly, this is an issue of first impression. Horizon submits that because Nautilus applies only to the bounds of claims that it should not be read so broadly as to apply to the basic and novel properties in construing "consisting essentially of." Actavis counters that because the basic and novel properties are part of defining

[7] The Court will not address the timing issues variously raised by the parties about the basic and novel properties.

the scope of the claim, Nautilus should apply to them as well. The Court agrees with Actavis that the basic and novel properties are part of the scope of the claim, and as such are part and parcel of the claims.

As a primary matter, the Federal Circuit has found that the definiteness requirement of 35 U.S.C. § 112, ¶ 2 applies to a "consisting essentially of" claim. See PPG Indus., 156 F.3d at 1354–55. For example, in PPG Industries, PPG held a patent for tinted glass used in automobiles, and filed an infringement action against Guardian, claiming that Guardian's glass product infringed PPG's patent. At the Markman phase, the district court was tasked with construing the following claim term: "A green tinted, ultraviolet absorbing glass having a base glass composition consisting essentially of: [various specific ingredients] and a colorant portion consisting essentially of: [various specific ingredients]." Id. at 1352. The parties agreed that that the basic and novel characteristics of PPG's glass were color, composition, and light transmittance. Id. at 1354. Guardian argued that its glass contained iron sulfide, an ingredient not listed in PPG's patent, as a colorant, and it therefore did not infringe. Id. at 1353.

PPG argued that the district court was required to determine as a part of claim construction whether iron sulfide could have a material effect on the basic and novel

characteristics of the claimed glass. Id. at 1354. If iron sulfide did not materially affect PPG's patented glass product, then Guardian's glass could be found to be infringing. The Federal Circuit affirmed the district court, which left the material-effect determination for the jury. The Federal Circuit explained,

> Claims are often drafted using terminology that is not as precise or specific as it might be. As long as the result complies with the statutory requirement to "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention," 35 U.S.C. § 112, para. 2, that practice is permissible. That does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.

Id. at 1355. The Federal Circuit emphasized that PPG's patent "contained some inherent imprecision resulting from the use of the term 'consisting essentially of.'" Id. It also emphasized that "PPG was entitled to provide its own definition for the terms used in its patent claim, including the transition phrase 'consisting essentially of,'" and that "PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and

novel characteristics of the invention." Id. The Federal Circuit found that because PPG failed to do so at the claim construction phase, whether the iron sulfide present in Guardian's glass materially affected the basic and novel properties of PPG's glass was for a jury to decide. Id.

The PPG Industries case affirms that claims containing the phrase "consisting essentially of" must meet the definiteness requirement of 35 U.S.C. § 112, ¶ 2, but the case also recognizes that the phrase itself is imprecise. In order to assess the definiteness of a patent claim that contains an imprecise phrase, the construction of the term "consisting essentially of" can be separated into two categories: (1) the specific listed ingredients or steps, and (2) the unlisted ingredients or steps that do not materially affect the basic and novel properties of the invention. At the claim construction phase, a court may construe the second category of a "consisting essentially of" claim term as long as the patent holder shows, through the specification and prosecution history, that a person skilled in the art would know that a particular unlisted ingredient could materially affect the basic and novel properties of the patent. If the patent holder fails to do so, a jury must determine whether an unlisted ingredient or step materially affects the basic and novel properties of the invention.

The lesson to be applied to this case, therefore, is that a court's assessment of the basic and novel properties may be performed at the claim construction phase because under certain circumstances the basic and novel properties of an invention are part of the construction of a claim containing the phrase "consisting essentially of."

The Supreme Court's decision in Nautilus simply reaffirms the long-established requirement that a patent's claims must be definite. The Supreme Court issued such a decision to make clear that centuries-old precedent applying the definiteness requirement of 35 U.S.C. § 112, ¶ 2, is still the standard today. See Nautilus, 134 S. Ct. at 2124, 2130 (finding that the current terminology "can leave the courts and the patent bar at sea without a reliable compass"). The Supreme Court directed, "In place of the 'insolubly ambiguous' standard, we hold 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." Id.

Through this direction, the Supreme Court recognized the delicate balance between the inherent limitations of language and the need for language precise enough to afford clear notice of what is claimed in order to avoid a zone of uncertainty for inventors. Id. at 2129. Indeed, the Supreme Court observed

that "absent a meaningful definiteness check . . . patent applicants face powerful incentives to inject ambiguity into their claims," and that "[e]liminating that temptation is in order." Id. (citations omitted). The Supreme Court noted that the "patent drafter is in the best position to resolve the ambiguity in patent claims." Id. (citation omitted).

After setting forth the redefined standard for assessing definiteness under 35 U.S.C. § 112, ¶ 2, the Supreme Court remanded the case to the Federal Circuit so that it could apply the standard to the claim at issue: a heart rate monitor that "'comprise[s],' among other elements, an 'elongate member' (cylindrical bar) with a display device; 'electronic circuitry including a difference amplifier'; and, on each half of the cylindrical bar, a live electrode and a common electrode 'mounted ... in spaced relationship with each other.' Id. at 2126 (noting that parties presented differing views on the definiteness of the term "spaced relationship").

The Nautilus decision replaced the Federal Circuit's amorphous standard for assessing whether a claim is indefinite with a standard that will allow only claims that meet the statutory definiteness requirement to stand. Because 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. Accordingly, the construction of the basic and novel properties is governed by 35 U.S.C. § 112, ¶ 2 and the accompanying analysis from Nautilus.

3. The Basic and Novel Properties of the Claimed Invention Are Indefinite

Horizon has identified five basic and novel properties for the claimed invention, relying on the specification of the '828 Patent: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. '838 Patent at 4:24–35, 9:1–10:47. Actavis argues that these are not identified as the basic and novel properties in the specification, and that these comparative terms do not provide the "reasonable certainty" required by Nautilus.

Relying on the canons of claim construction, the Court agrees with Horizon that the specification does identify these five properties as the "Characteristics of the Gel Formulation." '838 Patent at 9:1–10:47. Further, these characteristics are identified early on in the summary of the invention as being the characteristics that demonstrate improvement over the prior art. '838 Patent at 4:23–35. This is sufficient to identify these as the basic and novel properties of the claimed invention. See

L'Oreal, slip op. at 1 n.2 (identifying basic and novel properties even when not clearly titled as such).[8]

The focus now shifts to Actavis' position that the identified basic and novel properties are indefinite under 35 U.S.C. § 112, ¶ 2. Actavis argues that these generic comparative terms are too imprecise to be definite. As an exemplar of their argument, Actavis points to the first identified basic and novel property -- better drying time.[9]

In the section of the specification that identifies the basic and novel properties, under the subheading for "Drying Time," the specification explains that "[r]elative to previously disclosed [liquid] compositions . . . the compositions of the invention dry quicker . . . . The 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."

[8] Even if the Court were to accept Actavis' invitation to extrapolate out the requirements of means-plus-function claiming under 35 U.S.C. § 112, ¶ 6 to require a clear identification, which it does not do so, the '838 Patent would accomplish this.

[9] The parties briefed the definiteness of the claim term "a greater drying rate" in their opening Markman briefs and submitted expert declarations on the issue. Subsequently, Horizon dropped claims including this term, and the issue was not briefed again in responsive Markman briefs or in responsive expert declarations.

'838 Patent at 10:5–21. No data is ever provided in the specification for this on-limb testing. This section of the specification then discusses how to test for drying time more quantitatively and refers to data from an example later in the specification. See '838 Patent at 10:22–30.[10]

Turning to Example 5 and Table 12 which discuss drying time, there is an apparent problem in the assertion from earlier in the specification that the claimed invention would be drier within thirty minutes. Example 5 is conducted using the "more quantitative[ ]" method, wherein the formulations are spread on a plate and weighed at various time intervals, with "dryness" being determined by the percentage of weight remaining on the plate. See '838 Patent at 21:38–22:49. Example 5 discusses three different gel compositions, all of which are embodiments of the claimed invention of the '838 Patent. See id. Of the three gel compositions, only two of the described compositions are "drier" than the prior art liquid comparative at thirty

[10] The specification refers to Table 11 and Figure 10. '838 Patent at 10:29–30. However, these contain transdermal flux data and not weight and drying time, whereas Table 12 and Figure 11 contain the weight and drying time data. Accordingly, the Court finds this is a typographical error and one a POSA reviewing the '838 Patent would readily understand to look to Table 12 and Figure 11 rather than Table 11 and Figure 10. Cf. Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200, 1215 & n.8 (Fed. Cir. 2008) (permitting courts to redraft claim language "when there is an obvious administrative or typographical error not subject to reasonable debate") (citing Hoffer v. Microsoft Corp., 405 F.3d 1326, 1331 (Fed. Cir. 2005)).

minutes. '838 Patent at Table 12. The third formulation shows 100% of the weight remaining at thirty minutes as compared to the prior art liquid comparative which shows 95.6% of its weight remaining. Id. Only at four hours does the third formulation begin to show that it is drier than the prior art liquid comparative (86.8% vs. 93%). Id.

The contradictions specifically within Example 5 are even more problematic. Example 5 claims that "even within the first five minutes, the three gel formulations displayed more rapid drying than the liquid formulation." '838 Patent at 21:63-65. This is simply not supported by the data, which shows that at five minutes the third formulation had 100.3% of its weight present as compared to 98.1% of the prior art liquid comparative. '838 Patent at Table 12.

In short, the specification describes two different methods for evaluating "better drying time," and the two methods do not provide consistent results at consistent times. Further, the claimed results are not seen across all formulations of the claimed invention, and when "dryness" is evaluated at any time shorter than four hours, not all formulations of the claimed invention actually exhibit "better drying time." Horizon's expert urges the Court to only evaluate the drying rate at the twenty-four hour mark. (See Walters Opening Decl. ¶¶ 89-96.) However, Dr. Walters' reasoning does not comport with the plain

language of the specification, as explained. Even considering his references to the prosecution history, these still do not provide any clarity on the appropriate time frame under which to evaluate the drying rate. (See id. ¶ 92; Walters Ex. P.) More persuasive is Dr. Kohn's reasoning that a POSA would not know under what standard to evaluate the drying rate of the claimed invention. (See Michniak-Kohn Decl. ¶¶ 23–31.)

The result is that the "better drying rate" basic and novel property is indefinite. If a POSA reading the patent would understand the five principles identified by Horizon to be the basic and novel properties of the claimed invention, then once one of them is indefinite, they all become problematic. As stated, the purpose of the requirement of 35 U.S.C. § 112, ¶ 2 is to "inform those skilled in the art about the scope of the invention with reasonable certainty." Nautilus, 134 S. Ct. at 2129. Once one property does not have "reasonable certainty," it follows that the group of properties itself does not have the requisite "reasonable certainty." Consequently, the term "consisting essentially of" must be construed as indefinite due to the inability for a POSA to have "reasonable certainty" about what the basic and novel properties of the invention are, and thus the POSA would lack "reasonable certainty" about whether an additional ingredient would materially alter the basic and novel properties of the claimed invention.

III. CONCLUSION

For the foregoing reasons, the disputed terms are all held to be indefinite under 35 U.S.C. § 112, ¶ 2.

Date: August 17, 2016
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.

APPENDIX D

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND LIMITED, et al.,	Civil No. 14-7992 (NLH/AMD)
Plaintiffs,	**OPINION**
v.	
ACTAVIS LABORATORIES, UT, INC., et al.,	
Defendants.	

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HILLMAN, District Judge

Before the Court is the motion of Plaintiff Horizon (Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.) for reconsideration (Docket No. 192) of the Court's August 17, 2016 Markman Opinion (Docket No. 188). Horizon is the current owner and assignee of the patents-in-issue and of the PENNSAID® 2% New Drug Application, which is the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of the pain of osteoarthritis of the knees.

Horizon has filed several Hatch-Waxman actions alleging patent infringement against generic companies seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents, and this particular action concerns Horizon's claims against Actavis Laboratories UT, Inc.

("Actavis").[1] Horizon brought this action[2] in response to Actavis' assertion that the generic copy of PENNSAID® 2% described in Actavis' Abbreviated New Drug Application No. 207238 ("ANDA"), if approved by the FDA, would not infringe any valid and enforceable patent owned by Horizon.

In the Markman phase of the case,[3] the Court was tasked with construing the following terms in the '838 Patent Family[4]:

A. "the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity"

B. "the formulation degrades by less than 1% over 6 months"

C. "consisting essentially of"

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[1] Another group of cases filed by Horizon against a generic company seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents is against Lupin Ltd. and Lupin Pharmaceuticals, Inc. Because the Court's findings in the Actavis actions directly impact the claims in the Lupin actions, Lupin filed a brief in opposition to Horizon's motion for reconsideration and appeared at the January 4, 2017 hearing on that motion. (See Civil Action No. 15-3051, Docket No. 137.)

[2] This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271.

[3] Claim construction is "an issue for the judge, not the jury." Markman v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996).

[4] There are nine patents asserted in this matter. Of these, five patents - U.S. Patent Nos. 8,252,838; 8,563,613; 8,871,809; 9,066,913; and 9,101,591 - are part of the "'838 Patent Family" and all agreed to have the same specification. The other four patents - U.S. Patent Nos. 8,546,450; 8,217,078; 8,618,164; and 9,132,110 - are part of the "'450 Patent Family" and similarly agreed to have the same specification.

The Court found each of these terms to be indefinite. (Docket No. 188 at 12, 14, 27.) Specially with regard to "consisting essentially of," the Court noted that Horizon identified five basic and novel properties for the claimed invention: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. (Id. at 23.) The Court found that the basic and novel property of "better drying time" was indefinite, which therefore caused the term "consisting essentially of" to be indefinite. (Id. at 27.)

Horizon has filed the instant motion for reconsideration, arguing that the Court erred in two ways:

> The Court did not consider the alleged "indefiniteness" on a claim-by-claim basis, but instead broadly held the term "consisting essentially of" to be indefinite. When claims requiring use of hydroxypropyl cellulose (HPC) as a thickening agent are considered as independent inventions, those claims should not be found to be indefinite because the test results for such inventions are consistent. The only evidence of alleged inconsistent testing results was in the context of different claimed inventions that require carbopol thickening agents; and
>
> The Court's finding of indefiniteness is based on allegedly "unrebutted" expert testimony that the patent discloses two methods for comparing drying rates, which provide inconsistent results. However, Horizon's responsive expert evidence on this issue was not presented to the Court because of an agreement between the parties to not brief the definiteness of "greater drying rate" in Responsive Markman briefs. At the time of the Markman briefing and Markman Hearing, Actavis had not sought leave to amend their contentions to include the argument that the basic and novel properties were themselves indefinite. Indeed, to date, the only indefiniteness argument presented with respect to

> "consisting essentially of" in Actavis' Contentions is that a person of ordinary skill ("POSA") cannot identify the basic and novel properties.

(Docket No. 192-1 at 7.) Horizon also objects to the Court's application of Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2129 (2014) to the analysis of the invention's basic and novel properties. (Docket No. 192-1 at 10.)

The Court will grant Horizon's request that it reconsider its Markman decision, but after having fully considered the parties' briefing and oral argument, the Court stands by its prior findings.[5]

With regard to Horizon's argument that it was precluded from fully presenting its evidence to support its construction

[5] A motion for reconsideration may be treated as a motion to alter or amend judgment under Fed. R. Civ. P. 59(e), or as a motion for relief from judgment or order under Fed. R. Civ. P. 60(b), or it may be filed pursuant to Local Civil Rule 7.1(i). The purpose of a motion for reconsideration "is to correct manifest errors of law or fact or to present newly discovered evidence." Max's Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999). A judgment may be altered or amended only if the party seeking reconsideration shows: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. Id. A motion for reconsideration may not be used to re-litigate old matters or argue new matters that could have been raised before the original decision was reached, P. Schoenfeld Asset Mgmt., L.L.C. v. Cendant Corp., 161 F.Supp.2d 349, 352 (D.N.J. 2001), and mere disagreement with the Court will not suffice to show that the Court overlooked relevant facts or controlling law, United States v. Compaction Sys. Corp., 88 F.Supp.2d 339, 345 (D.N.J. 1999).

of the term "better drying time," the Court does not agree. The timeline of events, detailed by Actavis in its presentation at the January 4, 2017 hearing, demonstrates that Horizon had ample notice of Actavis's indefiniteness challenge to "better drying time," and several opportunities – including during the two Markman hearings on March 2, 2016 and June 7, 2016, the supplemental briefing in between, and during the ten weeks after the second Markman hearing and the issuance of the Court's Markman Opinion on August 17, 2016 – to voice its concerns about presenting all of its evidence to support its construction of "better drying time."

Similarly, Horizon chose to present its position on the `838 Patent Family as a whole, and has only raised the request that each claim of every patent should be considered individually in its motion for reconsideration. It is clear that Horizon was not "sandbagged" by the course of the claim construction process that took place over many months.

Even considering, however, Horizon's belated arguments to support its construction of "better dying time" and request for claim-by-claim construction, the Court comes to the same conclusion as detailed in the Markman Opinion. As the Court summed up its analysis, (1) the specification describes two different methods for evaluating "better drying time," and the two methods do not provide consistent results at consistent

times, (2) the claimed results are not seen across all formulations of the claimed invention, and when "dryness" is evaluated at any time shorter than four hours, not all formulations of the claimed invention actually exhibit "better drying time," and (3) Horizon's expert Dr. Walters' reasoning does not comport with the plain language of the specification, and his references to the prosecution history do not provide any clarity on the appropriate time frame under which to evaluate the drying rate, while Actavis' expert Dr. Kohn is more persuasive that a POSA would not know under what standard to evaluate the drying rate of the claimed invention. (Docket No. 188 at 26-27.) Thus, Horizon's requested relief in its motion for reconsideration, even if granted, does not change the Court's conclusion.

Putting aside the construction of "better drying time," the finding that the term "consisting essentially of" is indefinite is also confirmed by the finding that the stability and degradation claims are indefinite. As noted above, one of the basic and novel properties of Horizon's claimed invention is "favorable stability." The Court did not specifically address this term in the context of assessing the definiteness of the basic and novel properties, but earlier in the Markman Opinion the Court extensively analyzed the terms "the topical formulation produces less than 0.1% impurity A after 6 months at

25°C and 60% humidity" and "the formulation degrades by less than 1% over 6 months." In construing those terms, the Court found that the identity of "impurity A" was unknowable to a reasonable certainty to a POSA. (Docket No 188 at 7-12.) The Court further found that the patent did not provide guidance on how to evaluate degradation because it was either equated with "impurity A", which had already been deemed indefinite, or could be determined by multiple methods for how to evaluate stability without further guidance. (Id. at 7-13.) Thus, the Court concluded that both terms relating to stability were indefinite.[6]

The finding that the claim terms relating to stability are indefinite renders the claim term "consisting essentially of" indefinite. This is because the basic and novel property of "favorable stability" is indefinite. As stated in the Court's Markman Opinion, if a POSA reading the patent would understand the five principles identified by Horizon to be the basic and novel properties of the claimed invention, then once one of them is indefinite, they all become problematic. (Id. at 27.) When one property does not have "reasonable certainty," it follows that the group of properties itself does not have the requisite "reasonable certainty." Consequently, the term "consisting

[6] Horizon has not specifically challenged this finding in its motion for reconsideration.

essentially of" must be construed as indefinite due to the inability for a POSA to have "reasonable certainty" about what the basic and novel properties of the invention are, and the POSA would lack "reasonable certainty" about whether an additional ingredient would materially alter the basic and novel properties of the claimed invention. (Id.) Thus, regardless of the Court's construction of "better drying time," the indefiniteness of the stability terms also warrants the finding that "consisting essentially of" is indefinite.

Finally, with regard to Horizon's argument that the standard for an indefiniteness analysis reiterated by the Supreme Court in Nautilis should not be performed as to the basic and novel properties, the Court stands by its Markman Opinion, which explained why Nautilis should, and does, apply here. (Id. at 17-23.)

Horizon's bases for reconsideration were ably briefed and argued at the January 4, 2017 hearing, such that Horizon persuaded the Court to reconsider its August 17, 2016 Markman Opinion. But after reconsideration, the Court is not persuaded to disturb the prior result.

An appropriate Order will be entered.

Date: January 6, 2017
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.

APPENDIX E

United States Court of Appeals for the Federal Circuit

HZNP FINANCE LIMITED, HORIZON THERAPEUTICS USA, INC.,
Plaintiffs-Appellants

v.

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

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.

ON PETITION FOR REHEARING EN BANC

CARYN BORG-BREEN, Green, Griffith & Borg-Breen LLP, Chicago, IL, filed a petition for rehearing en banc for plaintiffs-appellants. Also represented by ROBERT FRITZ GREEN, JESSICA TYRUS.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, filed a response to the petition for defendant-cross-appellant. Also represented

by KRISTINA CAGGIANO KELLY, MICHAEL E. JOFFRE, WILLIAM H. MILLIKEN.

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

LOURIE, *Circuit Judge*, with whom NEWMAN, O'MALLEY, and STOLL, *Circuit Judges*, join, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

O R D E R

A petition for rehearing en banc was filed by appellants HZNP Finance Limited and Horizon Therapeutics USA, Inc. A response to the petition was invited by the court and filed by cross-appellant Actavis Laboratories UT, Inc. The petition for rehearing was first referred to the panel that heard the appeal, and thereafter, the petition for rehearing en banc and the response were referred to the circuit judges who are in regular active service. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

1) The petition for panel rehearing is denied.

2) The petition for rehearing en banc is denied.

3) The mandate of the court will issue on March 3, 2020.

FOR THE COURT

February 25, 2020
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

United States Court of Appeals for the Federal Circuit

HZNP FINANCE LIMITED, HORIZON THERAPEUTICS USA, INC.,
Plaintiffs-Appellants

v.

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

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

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LOURIE, *Circuit Judge*, with whom NEWMAN, O'MALLEY, and STOLL, *Circuit Judges*, join, dissenting from the denial of the petition for rehearing en banc.

I respectfully dissent from the court's decision not to rehear this case en banc. I believe the panel majority, affirming the district court, has erroneously misconstrued the "consisting essentially of" language in evaluating the definiteness requirement of 35 U.S.C. § 112.

The petition for rehearing asserts that the panel erred in holding that the claims reciting "consisting essentially

of" are indefinite because the basic and novel properties that the specification indicates the claimed composition possess are indefinite. I agree with the petition.

It is not disputed that "consisting essentially of" generally means that the composition not contain, in addition to its enumerated components, materials that materially affect the basic and novel properties of the invention. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). The majority here, affirming the district court, concluded that the claim was indefinite because of inconsistencies in the meaning of "better drying time."

However, better drying time is not in the claim, and it is the claims that the statute requires be definite. Claim 49 of U.S. Patent 8,252,838 ("the '838 patent"), at issue, certainly is definite on its face. It reads:

> 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. It recites diclofenac, the main active ingredient of the composition, three other specific excipients, all with precise and definite quantity ranges; one more excipient with no range; and the remainder consisting of water. Drying time is not recited.

The "consisting essentially of" language connotes that those specified are the claim's essential ingredients, but it is not closed to others. The word "essential" is key. The

possibility of inclusion of others, implied by the language at issue here, does not make what is recited and essential indefinite.

The utility of the claimed invention, recited in the specification, is as an anti-inflammatory, or analgesic, because those are the principal properties of diclofenac, the main ingredient of the composition. The specification also indicates that the advantages of the claimed composition are better drying time, higher viscosity, increased transdermal flux, greater pharmacokinetic absorption, and favorable stability. '838 patent col. 4 ll. 22–27. This disclosure informs the public about the nature of the claimed invention and may satisfy other requirements of § 112 as well as the utility requirement of § 101. These advantages are certainly relevant to showing that an invention has utility and may be important in overcoming a rejection for obviousness. But it is the language of the claims that must not be indefinite, not the understanding or clarity of an advantage of the invention. The advantages of the invention, its utility and its basic and novel properties, are not in the claims.

Aside from the specifics of "better drying time" in this case, the issue is of broader importance. Advantages of an invention recited in the specification or in the prosecution history, but not in the claims, are not part of the claims. Certainly the written description should be consulted to interpret claims, as they are drafted to be read together. *See* 35 U.S.C. § 112 (2010) ("The specification shall contain a written description of the invention . . . [and] shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."). But the advantages of an invention and disclosure of how to make and use an invention are not to be incorporated into claims for purposes of evaluating their indefiniteness. It is the language of the claims that determines their definiteness.

The language at issue here, "consisting essentially of," is clear, definite, language indicating that the constituents of a claim cannot include materials that affect the basic and novel properties of the claimed composition. Such materials may exist in an almost infinite variety. Certainly, such a claim should not be successfully asserted against a composition that contains materials that render the composition unfit for its stated purpose. But until a suit arises, one does not know what such an inconsistent material might be. That does not make the claim indefinite.

In an infringement suit, the meaning of the "consisting essentially of" language should boil down to a fact question, *i.e.*, whether the presence of an unrecited material in an accused product is in fact inconsistent with, or defeats the purpose of, the claimed composition. *See PPG*, 156 F.3d at 1357 (holding that, for a claim reciting glass "consisting essentially of" certain materials, the district court properly "left it to the jury to determine whether the amounts of [an unclaimed ingredient had] a material effect on the basic and novel characteristics of the glass"). There may be no question that a poison, such as arsenic, might be excluded from a claim. But the fact that one generally has to determine this question at trial does not make the claim indefinite. To hold to the contrary is to vitiate established usage that indefiniteness of claims is to be determined based on what the claim recites, not advantages cited in the specification.

An example of how converting uncertainty concerning measuring a property of an invention into indefiniteness of claims may lead to unintended and incorrect results is as follows:

Assume a claim recites a new and nonobvious compound, the usual situation of invention of a new pharmaceutical, not a composition of several components as here. It is not necessary under our law to recite in the claims the utility of the claimed compound, say, as an anti-

inflammatory. That is stated in the specification. It is also, under current law, unnecessary to recite in the claims how that effect is measured. The utility or advantage of the claimed compound are not generally challenged in examination unless they are not credible. MPEP § 2107 (9th ed. Rev. 08.2017, Jan. 2018). Thus, aspects of the utility or its measurement are not relevant to indefiniteness of the claims. And since how one measures anti-inflammatory activity does not create an indefiniteness issue, why should measuring better drying time? In fact, one wonders whether, if this patent did not recite the methods by which better drying time was measured, any indefiniteness of the "consisting essentially of" language would have arisen at all. Unfortunately, under the rule this opinion purports to adopt, any uncertainty concerning advantages, utility, or methods of determining such could, wrongly in my view, be translated into indefiniteness of claims.

To be sure, this example does not deal with the "consisting essentially of" language, but the principle of importing an uncertainty in measuring an advantage of an invention could have unintended potential effects well beyond this particular case. It should not be sound precedent.

I therefore respectfully dissent from the court's decision not to rehear this case en banc to clarify that the "consisting essentially of" language does not render these and similar claims that do not recite advantages of an invention or methods of measuring them indefinite.