

**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

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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

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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

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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.

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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.