

Keywords: “Reasonable certainty” standard, 112 Indefiniteness, “basic and novel” properties, “consisting essentially of” transition phrase

General: When interpreting formulation claims that include “consisting essentially of” language the reasonable certainty standard for indefiniteness must be applied to the “basic and novel” properties of the invention.

HZNP Medicines LLC v. Actavis Laboratories UT, Inc.
(2017-2149 Fed. Cir. 2019)
October 10, 2019

I. Facts and Procedural History

HZNP Medicines LLC (hereinafter, “Horizon”) is the assignee of a first group of method-of-use medical patents and of a second group of formulation patents. Both groups are listed in the U.S. Food and Drug Administration’s Orange Book for Horizon’s PENNSAID® 2% product. Actavis Laboratories UT, Inc. (hereinafter “Actavis”) sought to market a generic version of PENNSAID® 2% and filed Abbreviated New Drug Application (“ANDA”) No. 207238. Based on the ANDA filings, Horizon filed suit alleging infringement of the patents-at-issue in the district of New Jersey on December 23, 2014. The district court issued a *Markman* order that found indefinite under 35 U.S.C. §112 three terms in the asserted claims found in the second group of formulation patents. First, the district court found that the term “impurity A” in the claims was indefinite under 35 U.S.C. §112(b). The court noted that the specification and claims never included a definition for “impurity A”, and that a person of ordinary skill in the art (hereinafter, “POSITA”) would find the identity of “impurity A” unknowable. Second, the district court found that the term “degrades” in recitations such as “the formulation degrades by less than 1% over 6 months” was indefinite because neither the claims nor the specification disclose a means to evaluate the degradation. Third, the district court found that term “consisting essentially of” was indefinite. To find the transition phrase “consisting essentially of” indefinite, the district court first identified the “basic and novel” properties of the invention as claimed, which include a “better drying time”, and stated that the “better drying time property” was to be incorporated in the scope of the claims. The “better drying time” property was found to be indefinite using the reasonable certainty standard, and therefore the “consisting essentially of” language was considered to be indefinite. Horizon appealed to the federal circuit.

II. Issues

- 1) Did the district court err in finding the term “impurity A” indefinite?
- 2) Did the district court err in finding the term “degrades” indefinite?
- 3) Did the district court err in finding the transition phrase “consisting essentially of” indefinite?

III. Discussion

1) No. The federal circuit noted that a POSITA would not have understood, with reasonable clarity, the scope of the claims reciting “impurity A.” The specification didn’t list or define what “impurity A” was. Instead, Horizon argued that a POSITA would understand that “impurity A” meant “USP Related Diclonfenac Compound A” because reference material, such as various pharmacopeias, show that the degradation of the active ingredient in the formulation claims, diclofenac sodium, degrades into the single known impurity known as “USP Related Diclonfenac

Compound A”. However, the claims recited that the impurity included the entire formulation, not just the formulation’s active ingredient. Horizon had also argued that the specification mentioned an experiment that could be used for finding the impurity. However, the federal circuit noted that details of the experiment were missing, such as the column, the mobile phase, and the flow rate, and that the missing details were needed for POSITA to find impurity A.

2) No. The term “degrades” was used, for example, in claim language such as “a topical formulation that “degrades by/at less than 1% over 6 months.” The federal circuit noted that Horizon had proposed a claim construction where the term “degrades” meant “less than 1% of Impurity A present in a formulation sample after the sample was maintained at 25C and 60% humidity for 6 months” as supported in the specification. However, the federal circuit stated that since “Impurity A” was indefinite then the term “degrades” was also indefinite.

3) No. The federal circuit agreed with the district court that for formulation claims, using the transition term “consisting essentially of” triggers analyzing the basic and novel properties of what was claimed. More specifically, the federal circuit stated that because ‘consisting essentially of’ allows unlisted ingredients to be added to the formulation so long as they do not materially affect the basic and novel properties, the court should analyze the basic and novel properties as part of the reasonable certainty standard and not only what is in the claim language.

In the present case, the basic and novel properties included (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. These 5 properties were identified based on the specification, which included 5 subheadings identifying the properties and their characteristics. The specification further highlighted these subheadings 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.” The federal circuit stated that once the basic and novel properties are identified, one would then apply the reasonable certainty standard so 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.”

As noted by the Supreme Court in *Nautilus*¹, the reasonable certainty standard provides that patent claims must be “viewed in light of the specification and prosecution history . . . [so as to] inform those skilled in the art about the scope of the invention with reasonable certainty.” In the instant case, the application of the reasonable certainty standard to the term “better drying time” would result in a POSITA not understanding the scope of the claims because the specification described two different methods for evaluating the drying time that did not provide consistent results.

IV. Conclusion

When performing claim construction on formulation claims that include “consisting essentially of” as a transition phrase, one must 1) determine the basic and novel properties of the invention, and 2) analyze the basic and novel properties using the reasonable certainty standard. The specification should be used to determine one or more basic and novel properties of the invention and each property should then be analyzed under the reasonable certainty standard.

V. Dissent

Judge Newman dissented in-part because she believes that incorporating into the scope of the claims an analysis of the basic and novel properties is not a correct application of section 112(b), is not correct as a matter of claim construction, and is not the law of patenting novel compositions. For example, section 112(b) is completely silent as to adding to the scope of what is being claimed, and a property, such as “better drying time” is not an ingredient in the claimed formulation.

VI. Petition for *en banc* rehearing

Horizon’s petition for *en banc* rehearing was denied over a dissent from Judge Lourie, joined by Judges Newman, O’Malley, and Stoll. The basic trust of the dissent was that “better drying time” is not claimed, and it is the claims that section 112(b) requires to be definite.