

Publications

Intellectual Property Alert: Claim Language “Consisting Essentially Of”: A Cautionary Tale

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HZNP Medicines LLC et al. v. Actavis Laboratories UT, Inc., No. 2017-2149 (Fed. Cir. Feb. 25, 2020) (“HZNP”) is a cautionary tale on the use of the claim term “consisting essentially of.” On October 10, 2019, a Federal Circuit panel affirmed the district court’s holding that the term “consisting essentially of” was indefinite because the patent at issue had disclosed inconsistent results to a novel property of the invention thereby rendering that novel property indefinite. *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 698-699 (Fed. Cir. 2019) (“HZNP1”). On February 25, 2020, the Federal Circuit denied HZNP’s request for a rehearing *en banc* with four judges dissenting. In writing for the dissent, Judge Lourie said the panel majority had “erroneously misconstrued the ‘consisting essentially of’ language in evaluating the definiteness requirement of 35 U.S.C. § 112.”

The claim at issue was claim 49 of U.S. Patent No. 8,252,838 (the ‘838 patent), which recited:

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.

In construing the claim, the district court held that “consisting essentially of” meant “consisting of only the specified materials and those that [did] not materially affect the basic and novel properties of the claimed invention.” *HZNP1* at 693. Neither HZNP nor Actavis disputed the district court’s interpretation. However, the parties disputed the use of the basic and novel properties as additional claim limitations implicated by virtue of the phrase “consisting essentially of.” These novel properties were now subject to the *Nautilus* definiteness standard. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

Specifically, “drying time” was cited as a novel property of the ‘838 patent. Because the ‘838 patent had cited two different methods for “drying time” and application of those methods disclosed inconsistent results, “drying time” and “consisting essentially of” were both held indefinite by the district court. *HZNP1* at 698-99. The Federal Circuit panel affirmed the district court’s holding. “[A] claim is indefinite if its language might mean several different things and no informed and confident choice is available among the contending definitions.” *Id.* The district court had not erred in “applying the *Nautilus* definiteness standard to the basic and novel properties of the [‘838 patent] and . . . concluding that the phrase ‘consisting essentially of’ was indefinite.” *Id.*

En banc, the Federal Circuit affirmed the panel ruling 8-4. The dissent, however, argued that 35 U.S.C. §112 required that the claims be definite, and reasoned that as “drying time” was not recited in the disputed claim, the language “consisting essentially of” was definite. The dissent argued that “[t]o hold to the contrary [was] to vitiate established usage that indefiniteness of claims [was] to be determined based on

what the claim recite[d], not advantages cited in the specification.” Indeed, the dissent posited whether, “if [the ‘838 patent did] not recite the methods by which better drying time was measured, [the] indefiniteness of the ‘consisting essentially of’ language [] have arisen at all.”

Practice Note

The ‘838 patent claimed a formulation *consisting essentially of* a certain set of ingredients, which triggered a *Nautilus* analysis of the novel properties of that formulation. Inconsistent results of one novel property rendered a claim indefinite in *HZNP*.

To avoid a similar fate, one might consider additional review of the examples provided in the specification directed to a claim’s novel properties and eliminating any inconsistent results before filing a patent application. In addition, five properties were cited to exemplify the novelty of the ‘838 patent, and each was subject to a *Nautilus* analysis. When drafting a specification, one may want to consider holding back on some novel properties and proffering them later in a Rule 132 Declaration, if needed. Lastly, an additional claim reciting a formulation *consisting of* the same certain set of ingredients would not have required a *Nautilus* analysis and would have likely remained valid. See also *HZNP1* at 699 n.8.