



Archetype IPSM

Federal Circuit Friday

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October 2019

In *HZNP Medicines v. Actavis* (October 10), the Federal Circuit found a claim using the transitional phrase "consisting essentially of" indefinite because the specification description of one of the basic and novel properties of the claimed formulation failed to inform a person of ordinary skill of the scope of the claimed invention with reasonable certainty. The claims at issue were to topical medicinal gel formulations *consisting essentially of* a listed set of ingredients.

1. Meaning and scope of "consisting essentially of."

As a transition phrase, "consisting essentially of" means that the claimed invention necessarily includes the listed components or steps but is open to unlisted components or steps that "do not materially affect the basic and novel properties of the invention."¹ It therefore falls between "comprises," which is open-ended and allows components or steps in addition to those that are expressly-stated in the claim² and "consisting of," which is closed-ended and does not allow components or steps in addition to those expressly-stated.³

When "consisting essentially of" is the transition phrase, the scope of the claim is partly defined by the basic and novel properties of the invention because infringement and validity depend on whether any additional, unlisted components or steps present in the accused device or the prior art materially affect the claimed invention's basic and novel properties.

In *HZNP Medicines*, the first critical issue was whether the specification identified the "basic and novel properties" of the claimed invention. The Federal Circuit found those properties identified clearly in the specification, in a section entitled "Characteristics of the Gel Formulation" that was subdivided into five subsections: "Transdermal Flux," "Viscosity," "Stability," "Drying Time," and "Pharmacokinetics." Each of the subsections "identifies the specific characteristic" and "includes relevant discussion about its importance," while "the specification further highlights these features as advantageous over prior art."

The second critical issue was how to evaluate the basic and novel characteristics for purposes of definiteness – *i.e.*, what legal standard to apply.

2. *Nautilus* definiteness standard applies to the "basic and novel properties of the 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."⁴

The patentee, HZNP, argued that the *Nautilus* definiteness standard applies only to claims and not to the specification's description of the basic and novel properties of the invention, and that consideration of the basic and novel properties was a fact issue to be determined in the infringement or validity phases rather than as part of claim construction.

¹ Citing *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998) and *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

² See, e.g., *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1327-28 (Fed. Cir. 1999) ("'comprising' . . . is inclusive or open-ended and does not exclude additional unrecited elements or method steps.").

³ See, e.g., *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004) ("'Consisting of' is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim."). For clarity, note that although "'consisting of' limits the claimed invention, it does not limit aspects unrelated to the invention." *Id.*

⁴ *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).

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The Federal Circuit disagreed, explaining that HZNP's argument was "misguided" because "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" and "cannot later escape the definiteness requirement by arguing that the basic and novel properties of the invention are in the specification, not the claims." Further, HZNP's argument "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," which is an issue of the scope of the claims and is evaluated as part of claim construction.

To understand what constitutes a material alteration of the basic and novel properties, "the specification and the prosecution history . . . must provide objective boundaries for those of skill in the art" per the *Nautilus* standard.⁵

Thus, the third critical issue was whether the description of the basic and novel properties was adequate under *Nautilus*.

3. Here, the description of the basic and novel properties fails under the *Nautilus* standard.

As to the basic and novel property "Drying Time," the specification states that the inventive compositions "dry quicker" than prior art compositions and provides two tests and resulting data. The first is an "*in vivo*" test in which "equal amounts of the two products are tested on opposite limbs." Using this test, the specification reports that "[w]ithin thirty (30) minutes the compositions of the invention are almost completely dry whereas a significant amount of the previously described liquid formulation remains."

The second is a more quantitative "*in vitro*" test in which "the residual weight of formulations" are measured "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." Using this test, the specification reports that "a difference is immediately noticeable, and becomes dramatically different by 4 hours" and that "even within the first five minutes, the three [embodiments of the inventive] gel formulations displayed more rapid drying than the liquid formulation."

However, the data for the *in vitro* test shows that one of the inventive gel formulations⁶ did not exhibit faster or greater extent of drying at either five minutes or at 30 minutes, which is inconsistent with the statements about the enhanced drying being "immediately noticeable" (for the *in vitro* test) or observable at 30 minutes (for the *in vivo* test). The Federal Circuit found no other time frame or other criteria in the specification by which to objectively evaluate drying time.

The Federal Circuit found that because "a claim is indefinite if its language might mean several different things and no informed and confident choice is available among the contending definitions," the inconsistencies in the specification about the basic and novel property of "better drying time" – in particular the lack of "consistent [test] results upon which a POSITA would be able to evaluate" that property – a person of ordinary skill could not determine the scope of the claims.

In sum, because the basic and novel property of improved drying time is indefinite, the use of the transition phrase "consisting essentially of" draws that indefiniteness into the claim, fatally poisoning it.

⁵ Slip Op. at 26; see also *id.* at 28 ("[I]f 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" and "[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.").

⁶ Labeled "F971" in Table 12 of the specification, reproduced at page 30 of the Slip Op.