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“Consisting Essentially Of” Claims Nixed at Federal Circuit

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In *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*,¹ the U.S. Court of Appeals for the Federal Circuit affirmed the district court’s holding that the transitional phrase “consisting essentially of” was indefinite as used in several claims of patents owned by HZNP Medicines LLC and Horizon Pharma USA, Inc. (“Horizon”).²

BACKGROUND

Horizon’s patents cover its PENNSAID 2% product, which is a non-steroidal 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. Claim 49 of U.S. Patent No. 8,252,838 (the “’838 patent”) is illustrative of Horizon’s formulation patents and recites:

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.

Prior to the appeal to the Federal Circuit, the district court found that the phrase “consisting essentially of” in claim 49 of the ’838 patent was indefinite. The district court noted that, under *PPG Indus. v. Guardian Indus. Corp.*,³ “consisting essentially of” limits a claim to the recited ingredients and any unlisted ingredients that would not materially affect the basic and novel properties of the invention.

The district court then determined that 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.

With respect to the “better drying time,” the district court found that two different methods were taught for evaluating the drying time, and those methods

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provided disparate results, with some of the formulations according to the claimed invention meeting the “better drying time” characteristic in one method but not the other. Based on the inconsistencies between the results from the two methods, the district court found that a person of ordinary skill in the art (“POSITA”) would not have had “reasonable certainty”⁴ regarding the scope of the basic and novel properties of the invention.

THE FEDERAL CIRCUIT’S DECISION

On appeal to the Federal Circuit, the majority of the three-judge panel affirmed the district court’s determination regarding the indefiniteness of “consisting essentially of.” First, the majority agreed that the five properties recognized by the district court are the basic and novel properties of Horizon’s patents, with each one being highlighted in the specifications by subheadings. The majority further “determined that the basic and novel properties of an invention are part of the scope of the claims in this case.”⁵ In support of this finding, the court discussed prior “consisting essentially of” cases,⁶ and asserted that “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.”⁷

On appeal to the Federal Circuit, the majority of the three-judge panel affirmed the district court’s determination regarding the indefiniteness of “consisting essentially of.”

Regarding the “better drying time” property, the majority held 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.”⁸ Consequently, Horizon’s “consisting essentially of” claims were affirmed as indefinite.

Although the majority assures that “the phrase ‘consisting essentially of’ is not per se indefinite,”

the opinion creates vulnerabilities for claims using this transitional phrase. For instance, even though Horizon’s patents described five basic and novel characteristics, both the district court and Federal Circuit focused on a single property, the indefiniteness of which was sufficient to invalidate the entire claim. In light of this decision, applicants and practitioners may reconsider using “consisting essentially of,” as doing so will presumably place large swaths of the specification under definiteness review.

THE DISSENT

In his dissent, Judge Newman alludes to a potentially safer route for defining claim scope equivalent to “consisting essentially of” by contending that the majority’s holding implies “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.”⁹

Although Judge Newman contends that “[t]his new rule is not in conformity with precedent,” practitioners deferring to the alleged new rule might draft a claim using “comprising” and including one or more basic and novel properties and the mode of measuring the same. Such a claim would require the listed ingredients and would exclude any unlisted ingredients yielding a formulation not having the recited properties, and thus would be substantially similar in scope to a “consisting essentially of” claim not reciting those properties while avoiding some of the uncertainties surrounding “consisting essentially of” that are highlighted in this case.

For owners and assignees of patents including “consisting essentially of” in their claims, Judge Newman warns that “[t]his new rule of claiming compositions casts countless patents into uncertainty.”

For owners and assignees of patents including “consisting essentially of” in their claims, Judge Newman warns that “[t]his new rule of claiming compositions casts countless patents into uncertainty.”¹⁰ However, while this is a precedential opinion, the majority attempts to limit its reach by stating:

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."¹¹

As such, patent owners may be able to defend their patents from indefiniteness challenges along the lines set forth in this case by distinguishing from the facts thereof, or by filing a reissue application to restructure any "consisting essentially of" claims included therein.

Notes

1. Appeal Nos. 2017-2149, 2017-2152, 2017-2153, 2017-2202, 2017-2203, and 2017-2206 (Fed. Cir. Oct. 10, 2019).
2. *Id.*, slip op. at 2, 33. A number of other issues were decided in the appeal. This article deals only with the indefiniteness of the "consisting essentially of" transitional phrase.
3. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).
4. 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, 910 (2014)).
5. *HZNP Medicines*, *supra* n.1, slip op. at 26.
6. Namely, *PPG Indus. and AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).
7. *HZNP Medicines*, *supra* n.1, slip op. at 28.
8. *Id.* at 32.
9. Dissent at 9.
10. *Id.* at 10.
11. *HZNP Medicines*, *supra* n.1, slip op. at 33.

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