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Term “Consisting Essentially of” Risks Indefiniteness and No Intent from ANDA Label’s Permissive Use

A split Federal Circuit panel recently upheld the district court’s judgment of invalidity and non-infringement because the phrase “consisting essentially of” rendered the asserted claims indefinite and the proposed ANDA label did not induce infringement. Although aspects of the decision are fact specific, practitioners should nonetheless remain mindful of a few key points.

In assessing the indefiniteness of the phrase “consisting essentially of,” the majority in *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*¹ explained that courts should first identify and assess the “basic and novel properties” of the claimed formulation during claim construction under the definiteness standard from *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). If any one of these properties is indefinite, then the phrase “consisting essentially of” would likewise be indefinite.

As to the indirect infringement issue, the majority held that Actavis’s proposed drug label did

not show evidence of a specific intent to induce infringement. Whereas the claimed method requires application of a second topical agent, Actavis’s proposed drug label permitted—but did not require—post-product application of sunscreen, insect repellent, or a second topical medication. Thus, even if a user applied a second topical agent as recited in the claims, the label alone would not encourage or promote that use.

Background

HZNP Medicines LLC and Horizon Pharma USA, Inc. (together, Horizon) are the assignees of various Orange Book-listed method-of-use patents and formulation patents covering the PENNSAID® 2% product. Actavis Laboratories UT, Inc. (Actavis) filed an Abbreviated New Drug Application (ANDA) seeking to market a generic version of PENNSAID® 2%. After Actavis provided Horizon with its Paragraph IV certification, Horizon filed suit, alleging that Actavis’s proposed drug label infringes Horizon’s patents.

The district court ultimately held, among other things, that (1) Horizon’s formulation patents that used the phrase “consisting essentially of” were indefinite, and (2) Actavis’s label did not induce infringement of the method-of-use patents. Horizon appealed.²

Majority Opinion

Indefiniteness: ‘Consisting Essentially of’

Horizon challenged the district court’s holding that the phrase “consisting essentially of” included in some of the formulation claims was indefinite. Affirming the district court’s decision, the majority noted that this phrase has the following “distinct meaning within [Federal Circuit] jurisprudence”: “permit[s] inclusion of components not listed in the claim, provided they do not materially affect the basic and novel properties of the invention.”³ Applying this meaning to its analysis, the majority next assessed what qualified as “basic and novel properties” of the claimed formulations before determining whether those properties were definite.

The majority agreed with the district court that the asserted formulation patents identify five basic and novel properties of the claimed formulations: (1) better drying time, (2) higher viscosity, (3) increased transdermal flux, (4) greater pharmacokinetic absorption, and (5) favorable stability.⁴ The specification not only lists each of these five properties as separate subheadings, but it also explains the importance of each and how these properties in the claimed formulation improve the prior art.⁵

The majority next explained that courts must apply the *Nautilus* definiteness standard at the claim construction stage to each of the basic and novel properties to assess whether any one fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. If any property were indefinite, the phrase “consisting essentially of” would be indefinite as well.

To support its position that the *Nautilus* definiteness standard applies, the majority explained that the use of “consisting essentially of” in the claims “incorporate[s] into the scope of the claims an evaluation of the basic and novel properties.”⁶ Thus, by using the phrase “consisting essentially of” in the claims, “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,” because this “contravenes the legal meaning associated with the phrase.”⁷

The majority therefore applied the *Nautilus* definiteness standard to the claimed formulation’s basic and novel properties. The majority agreed with the district court’s determination that the basic and novel property of “better drying time” was indefinite because the specification provided two different methods for evaluating “better drying time” that failed to provide consistent results at consistent times.⁸ Thus, the majority concluded that the basic and novel property of “better drying time” is indefinite, which renders the entire phrase “consisting essentially of” indefinite.

The majority stressed that “the phrase ‘consisting essentially of’ is not *per se* indefinite”⁹ and that its holding does not require “that the patent owner draft claims to an untenable level of specificity.”¹⁰ Instead, it explained 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

Finally, the majority addressed Judge Newman’s dissenting opinion (discussed below) that the claimed formulation cannot be indefinite as it expressly claims a list of ingredients.¹² Relying on the

“well-established ‘principle that claim language should not [be] treated as meaningless,” the majority noted that the dissent’s position would “render the claim meaningless because it would have us read the term ‘essentially’ out of the phrase ‘consisting essentially of,’ resulting in the separate and distinct claim phrase, ‘consisting of.’”¹³

Induced Infringement: Permission Does Not Amount to Encouragement

Horizon also challenged the district court’s finding that Actavis’s label did not induce infringement of the method-of-use patents.¹⁴ According to Horizon, Actavis’s label tracks closely with the asserted claims, thereby proving Actavis’s specific intent to induce infringement.¹⁵

The majority rejected Horizon’s arguments and affirmed. Looking first to the claim language, the majority explained that the method claim requires three distinct steps: (1) applying the claimed formulation, (2) waiting for the area to dry, and (3) applying sunscreen, insect repellent, or a second topical medication.¹⁶

Actavis’s label, in contrast, instructs a user to do the following:

- Apply diclofenac sodium topical solution to clean, dry skin. (2.1)
- Dispense 40 mg (2 pump actuations) directly onto the knee or first into the hand and then onto the knee. Spread evenly around front, back and sides of the knee. (2.1)

...

- Wait until area is completely dry before covering with clothing or applying sunscreen,

insect repellent, cosmetics, topical medications, or other substances. (2.2)

...

- Avoid wearing clothing over the diclofenac sodium topical solution-treated knee(s) until the treated knee is dry.
- Protect the treated knee(s) from natural and artificial sunlight.
- Wait until the treated area is dry before applying sunscreen, insect repellent, lotion, moisturizer, cosmetics, or other topical medication to the same knee you have just treated with diclofenac sodium topical solution.
- Until the treated knee(s) is completely dry, avoid skin-to-skin contact between other people and the treated knee(s).¹⁷

Comparing the method claim’s steps to the label’s instruction, the majority concluded that the label does not encourage infringement because it only requires the first step of applying the claimed formula; it makes the remaining steps optional—that is, *if* a user wants to cover the treated area, *then* the user should wait until the area is dry.¹⁸ And even so, the label warns the user to wait until the treated area is dry before covering the area with not only “a sunscreen, or an insect repellent”—as recited in the claim—but also clothing, cosmetics, lotion, water, moisturizer, and other topical substances.¹⁹

Because the label does not *require* subsequent application of other products, the majority further reasoned that the label indicates substantial noninfringing uses.²⁰ As such, intent to induce infringement could not be inferred even if Actavis had actual knowledge that some users may infringe the patent.²¹ In short, although the evidence when viewed in Horizon’s

favor established that some users *may* infringe, it did not establish that the label in fact instructs users to infringe.²²

Judge Newman Concurring in Part, Dissenting in Part

Indefiniteness: “Consisting Essentially of”

Judge Newman first dissented from the panel majority’s holdings that (1) the claim term “consisting essentially of” rendered the claims indefinite, and (2) the knowledge of persons skilled in the art cannot fill any gap in providing the properties of compositions claimed with that term.²³ According to Judge Newman, using the term “consisting essentially of” does not invalidate the claims when the specification describes the claimed formulation’s properties, regardless of whether the claims repeat those properties.²⁴

Criticizing the majority’s refusal to consider information in the *US Pharmacopoeia* when the claim is in the form “consisting essentially of,” Judge Newman reiterated that “knowledge in the field of the invention must always be considered” where “definiteness is to be evaluated from the perspective of someone skilled in the relative art.”²⁵

In addition, Judge Newman rebuked the majority’s distinction between “consisting of” and “consisting essentially of” as “unsupported in precedent.”²⁶ She acknowledged that precedent distinguishes the two phrases and teaches that “‘consisting of’ limits the claimed invention [without] limit[ing] aspects unrelated to the

invention”; “[h]owever, no precedent has held that ‘consisting essentially of’ composition claims are invalid unless they include the properties of the composition in the claims.”²⁷

Judge Newman further accused the majority of ignoring the clear and convincing evidence standard for establishing invalidity for indefiniteness.²⁸ In Judge Newman’s view, there was no evidence—let alone clear and convincing evidence—that persons of ordinary skill in the art would not have understood the components of the composition claims with reasonable certainty.²⁹

Induced Infringement

Judge Newman next dissented from the majority’s holding that Actavis cannot be liable for induced infringement where a user might not follow the label’s instructions.³⁰ In particular, she reasoned that the majority opinion effectively created a new rule: “[T]he provider of the product with instructions to use it in accordance with the infringing method cannot be liable for inducement to infringe.”³¹

That patients may not always comply with instructions “does not insulate the provider from infringement liability,” Judge Newman explained.³² Therefore, in her view, the summary judgment of noninfringement was “incorrect in law.”³³

Conclusion

Although aspects of the majority’s decision are fact specific, practitioners should nonetheless remain mindful of the following key points. First, although the phrase “consisting essentially of” is not per se indefinite, each basic and novel property of the claimed invention must satisfy the *Nautilus*

definiteness standard. Failure to do so may render the phrase “consisting essentially of” indefinite and the claim invalid. Second, if a generic’s proposed drug label mentions but does not require users to perform all of the patented method’s precise steps, the label alone may be insufficient to create a material issue of fact concerning specific intent to induce infringement.

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1. Nos. 2017-2149, -2152, -2153, -2202, -2203, -2206, slip op. (Fed. Cir. Oct. 10, 2019).
2. Actavis cross-appealed the district court's judgment of nonobviousness. For brevity, this LawFlash does not address this issue.
3. *HZNP Meds.*, slip op. at 22 (internal citations omitted).
4. *Id.* at 23.
5. *Id.*
6. *Id.* at 24.
7. *Id.*
8. *Id.* at 29–30.
9. *Id.* at 24.

10. *Id.* at 33.
11. *Id.*
12. *Id.* at 21.
13. *Id.* at 21.
14. *Id.* at 34, 37–38.
15. *Id.* at 37–38.
16. *Id.* at 39.
17. *Id.* at 35.
18. *Id.* at 39–40.
19. *See id.* at 30, 35, 39.
20. *Id.* at 40.
21. *Id.*
22. *Id.*

23. Dissent at 2.
24. *Id.* at 5–6.
25. *Id.* at 8.
26. *Id.* at 9–10.
27. *Id.* at 10.
28. *Id.* at 11.
29. *Id.*
30. *Id.* at 12.
31. *Id.*
32. *Id.*
33. *Id.*

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