



Portfolio Media, Inc. | 111 West 19th Street, 5th floor | New York, NY 10011 | www.law360.com  
 Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

# High Court Should Review Horizon Arthritis Drug Patent Case

By **Paul Michel and John Battaglia** (September 8, 2020, 12:24 PM EDT)

So much patent-law attention today focuses on Title 35 of the U.S. Code, Section 101, and the ever-emerging ineligibility case law, and perhaps rightly so. The problem arises when another legal basic gets lost in the judicial shuffle, risking damage to core patent rights and doctrine if left uncorrected. And that is a primary reason why, in our view, the U.S. Supreme Court should grant certiorari in HZNP Medicines LLC v. Actavis Laboratories UT Inc.[1]

Patent rights and patent litigation largely hinge on determinations about the patent's claims, whether the issue is infringement, indefiniteness, invalidity or damages.[2] As former Federal Circuit Chief Judge Giles Rich famously put it in 1990, "The name of the game is the claim." [3]

HZNP is all about the claims. The case and petition ask the Supreme Court to address the primacy of claim language, the U.S. Court of Appeals for the Federal Circuit's holding that the claims there were indefinite based on disclosures in the specification, and its holding that the long-accepted transitional phrase used in those claims — "consisting essentially of" — had so rendered the claims invalid.

As we see it, the Federal Circuit's decision has also effectively rewritten Title 35 of the U.S. Code, Section 112, erroneously restricting claims that use this "consisting essentially of" phrase to the properties disclosed in the specification.

Further, it disregarded some 70 years of precedent and practice in which "consisting essentially of" became a well-known term of art, never a trigger for indefiniteness. And it is contrary to the Supreme Court's recent precedents on indefiniteness (per its 2014 decision in *Nautilus Inc. v. Biosig Instruments Inc.*) and claim construction fact-finding (per its 2015 decision in *Teva Pharmaceuticals USA Inc. v. Sandoz Inc.*).

Big enough for certiorari and the high court's review? We think so.

## The Federal Circuit's Holding

The background here merits attention. Plaintiffs Horizon and HZNP are the patent holders on claims relating to Pennsaid, a U.S. Food and Drug Administration-approved topical solution that treats pain for osteoarthritic knees. They sued Actavis for patent infringement following Actavis' assertions and Paragraph IV certification to the FDA that its generic version of the solution wouldn't infringe any valid claim of the plaintiffs.[4] But following the parties' claim construction hearing, the district court held the claims invalid as indefinite under Title 35 of the U.S. Code, Section 112(b).

A 2-1 Federal Circuit majority affirmed. In their reasoning, the composition claims there used the transitional phrase "consisting essentially of" before reciting certain ingredients in the claimed composition. By using that phrase, they continued, the patentees had thereby "incorporated into the scope of the claims an evaluation of the [invention's] basic and novel properties." [5] The majority cited no authority for this incorporation theory.[6] Nonetheless, it held the claims indefinite because of alleged inconsistencies with the meaning of "better drying time" — one of the five properties described in the patent's specification, but



Paul Michel



John Battaglia

appearing nowhere in the composition claims.[7]

In the majority's view, then, "the district court did not err in its determination that a [person of ordinary skill in the art] would not know under what standard to evaluate the [specification's disclosed] drying rate of the invention, thus rendering the basic and novel property of 'better drying rate' indefinite." [8]

U.S. Circuit Judge Pauline Newman dissented. In late February 2020, the full Federal Circuit declined by an 8-4 vote to take the case en banc. U.S. Circuit Judge Alan Lourie dissented from the court's en banc denial, issuing an opinion joined by three other Federal Circuit judges.

### **Why the Decision Warrants Supreme Court Review**

HZNP's petition provides several compelling reasons why the Supreme Court should take the case, and dissenting opinions by Judges Lourie and Newman likewise highlight fundamental errors with the panel's analysis. From our perspective, the case assuredly warrants the court's review, for three main reasons.

#### ***The claim indefiniteness analysis should assess and turn on the language of a claim — not a description in the specification.***

First, and most broadly, the panel's decision would turn the indefiniteness analysis on its ear. That is so because while the panel held the claims indefinite under the Patent Act's provision on claim sufficiency, see Section 112(b) — it did so without ever relying on any actual claim text to make that determination.[9]

The panel instead relied on the specification and its description of a characteristic ("better drying time") to make that claims-insufficiency decision.[10] In addition to the plain meaning of Section 112(b), the Supreme Court in *Nautilus* explained that "a claim is invalid for indefiniteness if its [claim] 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." [11]

Indeed, as the Supreme Court, scores of precedents, and Judge Lourie's dissent explain, the indefiniteness inquiry focuses on the claim language itself, Section 112(b) — not on the specification's disclosure about how to make and use the invention, see Section 112(a).[12] "Claims claim" and "the specification teaches." [13]

Accordingly, the majority has fundamentally changed the Supreme Court's claim indefiniteness test. The name of the game would no longer be the claim — not with HZNP standing in as the Federal Circuit's supposed interpretation of *Nautilus*. As the parties have explained, that change alone would affect tens of thousands of patents and throw into disarray whether and how a patent claim is now indefinite, because of something in the specification.

#### ***For 70 years, "consisting essentially of" had a well-known and definite legal meaning — only this case has found it "indefinite."***

Second, the transitional claim phrase at issue here — "consisting essentially of" — has a well-established and definite legal meaning. The phrase means that the composition (for example) includes the elements explicitly recited in the claim itself, and any additional unclaimed elements, provided those additional elements "do not materially affect the basic and novel characteristics of the inventions." [14]

Thus, if a claim recites a formula that "consists essentially of" compositions A and B, and another formula includes compositions A, B and C, that claim will still cover compositions A, B and C if the addition of C doesn't make that A-B-C formulation materially different from the A-B formulation's "basic and novel characteristics." [15]

As HZNP's petition emphasizes, some 70 years of precedent has approved this term's definition — indeed, this case stands as the first time that a court has held such a "consisting essentially of" claim indefinite. Perhaps unsurprisingly, then, the panel's decision also doesn't mention the burden of proof. Actavis surely had to overcome the presumption of validity and prove indefiniteness by clear and convincing evidence — a point that *Nautilus* declined to address, but that accords with the Patent Act and recent precedent.[16]

The Federal Circuit panel instead reasoned that this term ("consisting essentially of") duly "incorporated" into the claims "an evaluation of the [invention's] basic and novel properties" — including the "drying time"

property described in the specification.[17] But that incorporation theory runs afoul of the long-standing principle that courts ordinarily interpret claims "in light of the" specification's disclosure — not by "incorporating it." [18]

Instead, by so incorporating specification disclosures into the claims, the majority erroneously engaged in a legal analysis akin to that of a claim written in means-plus-function format under Section 112(f).[19]

***Underlying fact questions do not render the claims indefinite, whether resolved at Markman or at trial.***

Third, as the Federal Circuit dissenters recognized, this term of art — "consisting essentially of" — not only has a well-established meaning in patent law, but also, in an infringement suit, often "boils down to a fact question"; namely, whether the unclaimed ingredients or elements have a "material effect" on the invention's "basic and novel characteristics." [20]

To be sure, as Judge Lourie's dissent explained, the presence of certain unclaimed compositions, such as arsenic, may indisputably be excluded from such a "consisting essentially of" claim without a hearing. But otherwise, the fact the parties may need a trial or other hearing to resolve this factual issue doesn't ipso facto render the claim indefinite. And that conclusion comports not only with *Nautilus*, but also with the landmark case that issued the following term, *Teva v. Sandoz*, wherein the court held that claim construction may indeed involve subsidiary factual questions.[21]

Otherwise, to the extent the panel suggested it was critical for the trial court to resolve these "consisting essentially of" factual issues before trial, lest it frustrate the notice function of the claims, that suggestion seems without basis.[22] The timing of that determination, whether via a claim construction hearing or at trial, is a matter left almost entirely to the discretion of the trial judge.[23]

The greater harms to public notice and the patent system, in our view, result from the two broader points discussed above and what the Federal Circuit's HZNP ruling has done to each, namely, (1) deciding claim indefiniteness based not on any claim language, but on properties incorporated from the specification; and (2) casting a judicial pall on the definiteness of a claim term, "consisting essentially of," that for decades had an established legal meaning — one that patent stakeholders understood and relied on.[24]

In so doing, the HZNP majority has done precisely what it emphasized courts must avoid for claim indefiniteness: It has disregarded *Nautilus*' caution against rulings that "promote the innovation-discouraging 'zone of uncertainty.' "[25]

---

*Paul Michel served for more than 22 years on the Federal Circuit, retiring on May 31, 2010. From Dec. 25, 2004, until his retirement, he also served as chief judge of the Federal Circuit. He was appointed distinguished scholar in residence by the Intellectual Property Owners Education Foundation following his retirement.*

*John Battaglia is a federal trial and appellate attorney. He has been a federal prosecutor and law clerk at the Federal Circuit and Eastern District of Virginia. In 2006, he was appointed deputy associate attorney general of the U.S.*

*The opinions expressed are those of the author(s) and do not necessarily reflect the views of Portfolio Media Inc. or any of its respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.*

[1] *HZNP Medicines LLC v. Actavis Laboratories UT*, 940 F.3d 680 (Fed. Cir. 2019), *reh'g en banc denied*, 950 F.3d 867 (Fed. Cir. Feb. 25, 2020) (per curiam).

[2] E.g., Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 Mich. L. Rev. 101, 105 (2005) ("The claims of a patent are central to virtually every aspect of patent law.").

[3] Giles S. Rich, *The Extent of the Protection and Interpretation of Claims—American Perspectives*, 21 Int'l Rev. Indus. Prop. & Copyright L., 497, 499 (1990).

[4] E.g., 35 U.S.C. §271(e)(2)(A)(authorizing infringement case when generic drug-maker provides paragraph (iv) certification that generic drug described in its Abbreviated New Drug Application (ANDA) doesn't infringe any valid claim of plaintiff's listed patents).

[5] HZNP, 940 F.3d at 693-94.

[6] See, e.g., *id.*

[7] *Id.*

[8] HZNP, 940 F.3d at 693-94, 698 (citing *Nautilus, Inc. v. Biosig Instruments, Inc.* , 572 U.S. 898, 901 (2014)).

[9] 35 U.S.C. §112(b) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."); *Nautilus*, 572 U.S. at 901.

[10] *Id.*

[11] *Nautilus*, 572 U.S. at 901.

[12] E.g., *Halliburton Energy Servs., Inc. v. M-I LLC* , 514 F.3d 1244, 1249 (Fed. Cir. 2008) ("If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds."); *Phillips v. AWH Corp.* , 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (discussing "bedrock principle of patent law that 'the claims of the patent define the invention'").

[13] *SRI Int'l v. Matsushita Elec. Corp.* , 775 F.2d 1107, 1131-32 & n.14 (Fed. Cir. 1985) ("Specifications teach. Claims claim.").

[14] *PPG Indus. v. Guardian Indus. Corp.* , 156 F.3d 1351, 1354 (Fed. Cir. 1998).

[15] E.g., *id.*

[16] 35 U.S.C. §282 ("[a] patent shall be presumed valid" and "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity"); *Microsoft Corp. v. i4i Ltd., P'ship* , 131 S.Ct. 2238, 2242 (2011).

[17] HZNP, 940 F.3d at 693-94.

[18] *Nautilus*, 572 U.S. at 901; *CCS Fitness, Inc. v. Brunswick Corp.* , 288 F.3d 1359, 1366-67 (Fed. Cir. 2002) (recounting claim-construction principles and lone statutory exception for incorporating specification disclosure via 35 U.S.C. §112(f) into claims written in means-plus-function format).

[19] 35 U.S.C. §112(f) (restricting claim elements written in means-plus-function format to the structure and equivalents clearly linked to it in the patent's specification).

[20] See, e.g., *PPG Indus.*, 156 F.3d at 1357 (holding that, for a claim reciting a glass "consisting essentially of" certain materials, the district court properly left it to the jury to determine whether certain unclaimed ingredients had a "material effect on the basic and novel characteristics of the glass").

[21] *Teva Pharm. USA, Inc. v. Sandoz, Inc.* , 135 S.Ct. 831, 840-42 (2015); *In re Papst* , 778 F.3d 1255, 1261 (Fed. Cir. 2015) (applying *Teva*).

[22] HZNP, 940 F.3d at 693-94.

[23] See, e.g., *Sofamor Danek Grp., Inc. v. DePuy-Motech, Inc.* , 74 F.3d 1216, 1221 (Fed. Cir. 1996).

[24] See generally *Cias, Inc. v. Alliance Gaming Corp.* , 504 F.3d 1356 (Fed. Cir. 2007).

[25] HZNP, 940 F.3d at 693-94.

All Content © 2003-2020, Portfolio Media, Inc.