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[Appealed from D. Del., Chief Judge Sleet]

Abbreviations

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Patent Trial and Appeal Board (formerly the Board of Patent Appeals and Interferences)
Commissioner	Commissioner of Patents and Trademarks
CIP	Continuation-in-Part
DJ	Declaratory Judgment
DOE	Doctrine of Equivalents
FDA	Food and Drug Administration
IDS	Information Disclosure Statement
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
NDA	New Drug Application
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SJ	Summary Judgment
TTAB	Trademark Trial and Appeal Board

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Examiners May Not Rely on Extrinsic Dictionary Definitions Inconsistent with Intrinsic Evidence for Claim Construction

Morgan E. Smith

Judges: Rader (author), Moore, Wallach

[Appealed from Board]

In *Tempo Lighting, Inc. v. Tivoli, LLC*, No. 13-1140 (Fed. Cir. Feb. 10, 2014), the Federal Circuit affirmed the Board's construction of "inert to light," as claimed in U.S. Patent No. 6,554,446 ("the '446 patent"). But the Court vacated the Board's determinations that prior art references did not disclose the "inert to light" limitation and that Tempo Lighting, Inc. ("Tempo") waived its alternative claim construction arguments by not filing a cross-appeal at the Board.

Tempo requested inter partes reexamination of the '446 patent after Tivoli, LLC ("Tivoli"), owner of the '446 patent, sued Tempo for patent infringement. Claim 1 of the '446 patent recites "[a] lighting apparatus comprising: a first extruded portion shaped to mount on the nose of a stair step; and, a second extruded portion coextruded with said first portion and mounted on top of the first portion so as to be above the nose of the stair step, said second portion comprising a material *inert to light* . . . ." Slip op. at 2 (citation omitted). The examiner, citing a dictionary, construed the term "inert to light" as "a material that either does not react, e.g. by degrading, when exposed to light or a material that does not react because it has been treated with or includes some additive, which inhibits degradation of the material when exposed to light." *Id.* at 3 (citation omitted). The examiner then adopted five of Tempo's sixty obviousness rejections. Tivoli appealed and Tempo's brief on appeal included arguments supporting the examiner's rejections and alternative grounds for upholding the examiner's determination using Tivoli's proposed claim construction for "inert to light."

The Board rejected the examiner's claim construction because Tivoli defined "inert to light" during prosecution of the '446 patent as "non-photoluminescent and not activated to glow by absorbing ambient light." *Id.* at 4 (citation omitted). After rejecting the examiner's claim construction and adopting Tivoli's definition of "inert to light," the Board still relied on the examiner's findings that the primary prior art references lacked the "inert to light" limitation. Finally, the Board concluded that Tempo waived its alternative arguments pertaining to anticipation by certain references because Tempo did not file a cross-appeal raising those arguments. Tempo filed a request for rehearing, which the Board denied.

"The examiner instead relied on an extrinsic dictionary definition of 'inert.' This extrinsic evidence is not irrelevant, but has relatively little probative value in view of the prevailing intrinsic evidence. In sum, the examiner erred by resorting to extrinsic evidence that was *inconsistent* with the more reliable intrinsic evidence." Slip op. at 7 (citation omitted).

"Thus, one of the threshold conditions for a cross-appeal is a final decision favorable to patentability. In this case, the examiner rejected all the claims. Thus, the record presented no decision favorable to patentability for Tempo to appeal." *Id.* at 9.

On appeal, the Federal Circuit first affirmed the Board's construction of "inert to light." The Court held that intrinsic evidence supported the Board's construction because Tivoli amended the claims to recite "inert to light" while also supplying a meaning for the limitation. The Court noted that the examiner's proposed construction, relying on dictionary definitions, lacked support from intrinsic evidence, and the examiner also erred "by resorting to extrinsic evidence that was *inconsistent* with the more reliable intrinsic evidence." *Id.* at 7. The Court further noted that the Board construed "inert to light" consistently with the specification and properly "avoided the circularity inherent in any attempt to construe claims with an eye to preserving their validity." *Id.* at 8. While the PTO generally need not accept a claim construction proffered as a prosecution history disclaimer, the Court held that, in this instance, it was appropriate because the PTO specifically requested that Tivoli rewrite the "non-photoluminescent" limitation in positive terms.

The Federal Circuit then vacated the Board's determination that the primary prior art references lacked the "inert to light" limitation. The Court held that the Board erred by relying on factual findings resting on the examiner's incorrect claim construction. The Court determined that the Board reasoned incorrectly because it only cited "the examiner's findings under the reversed—and substantially different—claim construction." *Id.* On remand, the Court instructed the Board to make new factual findings under the proper construction.

The Federal Circuit also held that the Board's refusal to consider Tempo's alternative arguments on appeal rested on a clearly erroneous interpretation of 37 C.F.R. § 41.61(b), which states that "a requester who has not filed a notice of appeal may file a notice of cross appeal *with respect to any final decision favorable to the patentability, including any final determination not to make a proposed rejection*, of any original, proposed amended, or new claim of the patent." *Id.* at 9 (quoting 37 C.F.R. § 41.61(b)). The Court noted a threshold condition for a cross-appeal is a final decision favoring patentability, and this case did not meet said threshold, as the examiner rejected all claims, "a decision decidedly unfavorable to patentability." *Id.* The Court reasoned that, even if 37 C.F.R. § 41.61(b) gave Tempo the right to raise its arguments in a cross-appeal, the regulation only stated that Tempo "may" do so, not that it must. The Court further reasoned that Tempo did not seek to enlarge its rights or lessen the rights of an adversary, both of which generally necessitate a cross-appeal. "Throughout the reexamination, Tempo argued that the primary references anticipate the claims under Tivoli's construction. While Tempo argued in favor of the examiner's construction and rejections, this did not foreclose Tempo from also advancing arguments under the construction proposed by Tivoli." *Id.* at 10-11 (citation omitted). Finally, the Court held that Tempo's conduct did not rise to the level of waiver or invoke judicial estoppel.

Accordingly, the Court affirmed the Board's construction of "inert to light" and vacated the Board's decisions that the primary prior art references lacked the "inert to light" limitation and that Tempo waived its alternative arguments by not filing a cross-appeal.

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An Invention Conceived by a Foreign Inventor and Reduced to Practice in the United States Qualifies as Prior Art Under § 102(g)(2)

Kara A. Specht

Judges: Rader, Newman (dissenting), Dyk (author)

[Appealed from D. Del., Judge Robinson]

In *Solvay S.A. v. Honeywell International Inc.*, No. 12-1660 (Fed. Cir. Feb. 12, 2014), the Federal Circuit held that an invention conceived by a foreign inventor and reduced to practice in the United States qualifies as prior art under pre-AIA 35 U.S.C. § 102(g)(2) (2006).

Solvay's patent, U.S. Patent No. 6,730,817 ("the '817 patent"), claims an improvement of a method for making a hydrofluorocarbon and has a priority date of October 23, 1995. In 1994, before the priority date of the '817 patent, engineers working at the Russian Scientific Center for Applied Chemistry ("RSCAC") under contract with Honeywell conceived of the same method claimed in the '817 patent. In July 1994, the personnel at RSCAC sent Honeywell a detailed report documenting the method. Honeywell personnel in the United States then used the RSCAC method to run the same process in this country prior to the '817 patent's priority date.

Solvay sued Honeywell, alleging that the process Honeywell was using infringed the '817 patent. Honeywell countered that the asserted claims were invalid under § 102(g)(2). Honeywell's theory was that "its engineers had reduced the invention to practice in the United States and that this made the Honeywell engineers inventors under § 102(g)(2)." Slip op. at 6. The district court ruled on SJ that Honeywell's process infringed the '817 patent, but also granted SJ of invalidity of the '817 patent under § 102(g)(2) on the ground that the Honeywell engineers were other inventors who made the invention in this country without abandoning, suppressing, or concealing it. The case was then appealed to the Federal Circuit where the Court reversed the finding of invalidity, "explaining that Honeywell personnel could not qualify as 'another inventor' because they 'did not conceive the invention . . . but derived it from others.'" *Id.* at 7 (quoting *Solvay S.A. v. Honeywell Int'l, Inc.*, 622 F.3d 1367, 1378-79 (Fed. Cir. 2010)). On remand, Honeywell asserted an alternate theory, arguing that "the Russian inventors made the invention in this country by sending instructions to Honeywell personnel who used the instructions to reduce the invention to practice in this country." *Id.* The district court determined that the Russian inventors should be treated as inventors who made the invention in the United States under § 102(g)(2), and the '817 patent was found to be invalid. Solvay appealed the holding of invalidity, as well as a claim construction applied by the district court.

"[T]he process invented by the Russian engineers was made in this country when Honeywell successfully performed the process because the Russians authorized Honeywell personnel to practice the invention and specifically contemplated that they would do so." Slip op. at 17.

On appeal, the Federal Circuit first addressed whether Solvay could raise the issue of claim construction. According to Solvay, the district court's jury instruction reflected an erroneous interpretation of the claim term "isolating," but the Court noted that Solvay did not raise the issue at trial and did not ask the district court to modify the claim construction or accompanying jury instruction. The Court held that because "Solvay failed to object to the court's construction . . . with respect to the term 'isolating,' it waived the issue." *Id.* at 11-12 (footnote omitted). Moveover, the Court held that even if Solvay had properly raised the claim construction issue, there was no error in the district court's construction.

The Court then addressed Solvay's argument that the requirements of § 102(g)(2) were not properly met. Solvay argued that "(1) the doctrine of inurement, defining when the activities of others inure to the benefit of the inventor, controls the question of whether Honeywell's work can be attributed to the RSCAC engineers, and (2) the undisputed facts do not establish inurement because the RSCAC engineers did not expressly ask the Honeywell researchers to perform the inventive process." *Id.* at 14. The Court noted that while no inurement can arise from a third party's unwarranted and hostile use of another's invention, "an express request or direction is not required," as the request may be implicit. *Id*. Thus, the Court determined that "case law does not support Solvay's contention that an inventor must make an express directive or request to benefit from a third party's reduction to practice." *Id*. at 16. The Court therefore agreed with the district court that "the process invented by the Russian engineers was made in this country when Honeywell successfully performed the process because the Russians authorized Honeywell personnel to practice the invention and specifically contemplated that they would do so."
Id. at 17. The Court therefore affirmed the district court's judgment that the '817 patent is invalid under § 102(g)(2).

Judge Newman dissented, stating that "[t]he new general rule here adopted contravenes the policy and the letter of patent law, wherein inventors are charged only with knowledge of what is known or knowable as defined by statute, subject to special limited circumstances." Newman Dissent at 1. In Judge Newman's view, "the court's ruling that prior art includes secret information is of far-reaching potential impact." *Id*. at 8.

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Plain and Ordinary Meaning Applied Where Patentee Did Not Clearly Express an Intent to Redefine the Claim Term

Flora M. Amwayi

Judges: Rader, Linn (author), Wallach

[Appealed from D. Del., Judge Robinson]

In *Butamax™ Advanced Biofuels LLC v. Gevo, Inc.*, No. 13-1342 (Fed. Cir. Feb. 18, 2014), the Federal Circuit vacated the district court's grant of SJ of noninfringement, finding that the district court erred in its claim construction, and reversed the district court's grants of SJ of invalidity.

Butamax™ Advanced Biofuels LLC ("Butamax") owns U.S. Patent Nos. 7,851,188 ("the '188 patent") and 7,993,889 ("the '889 patent"), which are directed to the production of isobutanol, useful as a fuel or food additive. The '188 patent is directed to a recombinant microbial host cell that uses a particular five-step biosynthetic pathway to produce isobutanol, and the related '889 patent is directed to a method of producing isobutanol from a recombinant yeast microorganism that expresses the five-step biosynthetic pathway. The second step of the biosynthetic pathway is a conversion that is catalyzed by a polypeptide enzyme known as keto-acid reductoisomerase, or "KARI."

Butamax sued competitor Gevo, Inc. ("Gevo") for infringement of the '889 and '188 patents, and moved for a preliminary injunction predicated on the '889 patent. The district court denied Butamax's motion based on its construction of the KARI term as "an enzyme that is solely NADPH-dependent." Slip op. at 8 (quoting *Butamax™ Advanced Biofuels LLC v. Gevo, Inc.*, 486 F. App'x 883, 883 (Fed. Cir. 2012)). On a prior appeal, the Federal Circuit affirmed the denial of Butamax's motion, but noted that the district court's construction of the KARI term was "very questionable" and asked the district court "to reconsider its construction when it holds the *Markman* hearing." *Id.* (quoting *Butamax™*, 486 F. App'x at 883). At the *Markman* hearing, the district court construed the term in the '889 patent as "an enzyme known by the EC number 1.1.1.86 that catalyzes the conversion of acetolactate to 2,3-dihydroxyisovalerate and is NADPH-dependent." *Id.* (citation omitted). The district court then, inter alia, denied a motion by Butamax for SJ of literal infringement, granted Gevo's motion for SJ of noninfringement under the DOE, granted Gevo's motion for SJ of invalidity of claims 12 and 13 of the '889 patent for inadequate written description, and also found claims 12 and 13 invalid for lack of enablement. Butamax appealed.

"It cannot be disputed that the patentees offered a definition of KARI. It is disputed, however, whether this definition 'clearly expresses an intent' to redefine KARI in a way that differs from the plain and ordinary meaning . . . and, if so, the extent of any such difference." Slip op. at 13.

On appeal, the Federal Circuit noted that the primary dispute between the parties was whether the claimed KARI must be "NADPH-dependent." The Court concluded that the plain meaning of KARI itself

did not impose this limitation, and further that the patentees did not act as their own lexicographers by defining KARI to be NADPH-dependent. The Court reasoned that while the patentees offered a definition for KARI, it did not clearly express an intent to redefine the term KARI as being NADPH-dependent. The Court also agreed with Butamax that the references in the specification to other enzymes as using certain cofactors like NAD+ or NADH and/or NADPH did not imply that the patentees intended to limit KARI to exclude use of NADH.

The Federal Circuit disagreed with Gevo's contention that the reference in claim 1 of the '188 patent to an Enzyme Commission ("EC") number for KARI required KARI to be NADPH-dependent. The Court noted that the EC number referred to a mutant in which NADH could substitute for NADPH, and that Gevo described its own mutant enzymes (which it contended are not NADPH-dependent) by reference to that same EC number. The Court stated it could not conclude that the reference to the EC number was an expression of a clear intent to redefine KARI. The Court also noted that the district court's claim construction improperly excluded a preferred embodiment, which was also the subject of a dependent claim, and that the prosecution history did not warrant any limitation of the claimed KARI as being NADPH-dependent. The Court thus construed the enzyme term without imposing the limitation that it be NADPH-dependent.

Turning to the district court's grants of SJ of infringement and invalidity, the Court first vacated the SJ of infringement and directed the district court to reconsider the question under the new claim construction. The Court then reversed the SJ of invalidity of claims 12 and 13 of the '889 patent, finding that the '889 patent provided adequate written description for these claims. The Court reasoned that Butamax identified sufficient evidence that at least created a genuine dispute of material fact. The Court also reversed the district court's judgment that these claims were invalid for lack of enablement, reasoning that "the judgment was a scrivener's error." *Id.* at 26.

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DOE Not Limited by the Foreseeability of Equivalents

Rob C. MacKichan

Judges: Moore (author), Clevenger, Reyna

[Appealed from W.D. Wash., Judge Martinez]

In *Ring & Pinion Service Inc. v. ARB Corp.*, No. 13-1238 (Fed. Cir. Feb. 19, 2014), the Federal Circuit held that application of the DOE is not limited by the foreseeability of equivalents, reversed the district court's grant of SJ of noninfringement based on claim vitiation, and remanded for the entry of judgment of infringement.

Ring & Pinion Service Inc. ("R&P") sought a DJ that its automotive locking differential product did not infringe ARB Corporation Ltd.'s ("ARB") U.S. Patent No. 5,591,098 ("the '098 patent"). After claim construction, the parties filed a joint stipulation regarding infringement. The parties agreed that R&P's product literally met all but one limitation of the asserted claims, the "cylinder means formed in . . ." limitation, but that the accused product contained an equivalent cylinder that would have been foreseeable to a person having ordinary skill in the art at the time the '098 patent was filed. Thus, according to the parties' stipulation, there were no issues of material fact regarding infringement under the DOE, and infringement depended solely on whether an equivalent is barred under the DOE because it was foreseeable at the time of the patent application.

The district court entered an order approving the parties' joint stipulation. And after requesting additional briefing to address the all-limitations rule, the district court held that foreseeability did not preclude application of the DOE, but that application of the DOE would vitiate the "cylinder means formed in . . ." limitation. Accordingly, the district court granted SJ of noninfringement for R&P. ARB appealed.

"There is not, nor has there ever been, a foreseeability limitation on the application of the doctrine of equivalents." Slip op. at 4.

The Federal Circuit held that "[t]here is not, nor has there ever been, a foreseeability limitation on the application of the doctrine of equivalents." Slip op. at 4. Rather, the Court explained that excluding equivalents that were foreseeable at the time of patenting would conflict with long-established holdings that "known interchangeability weighs in favor of finding infringement under the doctrine of equivalents." *Id.*

The Court addressed the primary cases relied on by R&P to support a foreseeability bar to application of the DOE. The Court first rejected as misplaced R&P's reliance on *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420 (Fed. Cir. 1997), which, according to the Court, held that claim vitiation, not foreseeability, prevented application of the DOE in that case because application of the DOE would have written express limitations out of the claim. The Court next rejected R&P's contention that

Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc., 145 F.3d 1303 (Fed. Cir. 1998), established a foreseeability limitation for means-plus-function limitations, explaining that *Chiuminatta* merely sets forth differences between the equivalence determinations made for literal infringement versus infringement under the DOE. The Court concluded that "[n]othing in *Chiuminatta* or in any other case cited by R&P supports its assertion that there exists a foreseeability exception to the doctrine of equivalents that applies to means-plus-function or any other claim terms." Slip op. at 7.

The Federal Circuit next addressed the district court's grant of SJ of noninfringement based on the district court's finding that application of the DOE would vitiate the "cylinder means formed in . . ." limitation. The Court held that because vitiation is "not an exception to the doctrine of equivalents, but instead a legal determination that the evidence is such that no reasonable jury could determine two elements to be equivalent," the district court erred by failing to enforce the parties' stipulation that there was equivalence. *Id.* at 9 (quoting *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed. Cir. 2012)). According to the Court, "[a] stipulation of fact that is fairly entered into is controlling on the parties and the court is generally bound to enforce it." *Id.* at 8. The Court also held that ARB had not waived its argument regarding enforcement of the joint stipulation by failing to raise it in response to the district court's request for supplemental briefing on the all-limitations rule. The Court concluded that the stipulation and the parties' briefing provided sufficient notice to R&P of the possible impact of the stipulation.

Accordingly, the Federal Circuit reversed the district court's grant of SJ of noninfringement and remanded with instructions to grant SJ of infringement for ARB.

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Mere Possibility of Different Results from Different Measurement Techniques to Determine a Claimed Value Does Not Render a Claim Indefinite

Kimberly D. Braslow

Judges: Prost (author), Plager, Chen

[Appealed from D.N.J., Judge Pisano]

In *Takeda Pharmaceutical Co. v. Zydus Pharmaceuticals USA, Inc.*, No. 13-1406 (Fed. Cir. Feb. 20, 2014), the Federal Circuit affirmed the district court's finding that U.S. Patent No. 6,328,994 ("the '994 patent") was not invalid, and reversed the district court's finding of infringement.

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc., and Ethypharm, S.A. (collectively "Takeda") own patents claiming the formulation of Prevacid® SoluTab™. When Zydus Pharmaceuticals USA, Inc. and Cadila Healthcare Limited (collectively "Zydus") filed an ANDA with the FDA seeking to manufacture a generic version of Prevacid® SoluTab™, Takeda filed suit, alleging that Zydus's product infringed claim 1 of the '994 patent. Zydus counterclaimed that claim 1 was invalid under 35 U.S.C. § 112. Claim 1 of the '994 patent encompasses orally disintegrable tablets comprising lansoprazole, the active ingredient of the product marketed as Prevacid® SoluTab™.

The district court construed the claim term "fine granules having an average particle diameter of 400 µm or less" of claim 1 to include a deviation of ±10%, i.e., fine granules having an average particle diameter of 360 µm-440 µm. Slip op. at 3. Under that construction and based on its determination of how the average particle diameter was measured, the district court found that Zydus's ANDA product infringed claim 1 of the '994 patent. The issue of infringement turned on whether the average particle diameter of the granules included measuring the agglomerated granules—granules fused together because of the coating process used to manufacture the granules—or whether the agglomerates were dissected individually before measurement. The district court found that the '994 patent required measuring the average particle diameter regardless of whether or not they were present as agglomerates. The district court further rejected Zydus's position that claim 1 was invalid under 35 U.S.C. § 112, and enjoined Zydus from manufacturing or selling its ANDA product until the '994 patent expired.

"However, we do not believe that the mere possibility of different results from different measurement techniques renders claim 1 indefinite. Rather, the evidence established that *both* methods of measurement accurately report average particle diameter; the experts agreed that 'the correct but differing particle size results obtained using various instruments are all equally correct, but each simply may be expressing its correct results in different terms.'" Slip op. at 11-12 (citation omitted).

On appeal, the Federal Circuit first held that the district court incorrectly construed the term "fine granules having an average particle diameter of 400 µm or less" to include a deviation of ±10%. The Court found that there was no indication in the claim language itself, the specification, or the prosecution history to support a broader diameter range than actually claimed. While Takeda argued that the word "about" was used in the specification to modify the term "average particle diameter of 400 µm or less," the Court found that those instances only referred to diameters lower than the claimed amount. *Id.* at 8. During prosecution, Takeda also distinguished the claimed invention over potentially invalidating art by arguing that the reference failed to teach or suggest an "average particle diameter of 400 µm or less." *Id.* The Court therefore concluded that "the inventors have consistently relied on 400 µm as the dividing line between granules that would avoid roughness in the mouth and those that would not—meaning those that were within the scope of the invention, and those that were not." *Id.* at 9. Accordingly, the Court found that the term should be limited to "fine granules having an average particle diameter of precisely 400 µm or less," and based on that construction, the Court found that Zydus's ANDA product, which has an average particle diameter of 412.28 µm, did not literally infringe claim 1 of the '994 patent. *Id.* at 9-10 (citation omitted).

The Federal Circuit then turned to the district court's finding that claim 1 of the '994 patent was valid. The central issue as to indefiniteness revolved once again around the method used to measure the average particle diameter of the claimed granules. While Zydus highlighted the failure of the '994 patent specification to provide sufficient information to determine which type of measurement technique could be used, the Court rejected the premise that "the mere possibility of different results from different measurement techniques [disclosed in the '994 patent's specification] renders claim 1 indefinite." *Id.* at 11-12. The Court noted that expert testimony indicated that both methods of measurement accurately reported the average particle diameter and further concluded that "there is no evidence that the differences between these techniques are in fact significant." *Id.* at 12. Thus, the Court concluded that Zydus failed to establish, by clear and convincing evidence, that claim 1 of the '994 patent was invalid for indefiniteness.

The Court also rejected Zydus's argument that claim 1 of the '994 patent lacked written description because the specification only discussed measuring the diameter pretableting and failed to demonstrate how to ensure whether the granules were present in the claimed average particle diameter when in tablet form. The Court concluded that Zydus's argument relied on there actually being an effect on particle size from the tableting process, and the evidence was to the contrary. Relying on testing performed by Takeda's expert, which showed that the compression technique did not affect the average particle diameter, the Court explained that, "here, the evidence established only a hypothetical possibility that tableting *could* affect particle size in a relevant way." *Id.* at 15. Based on that evidence, the Court simply could not conclude that the district court committed clear error.

Finally, the Court rejected Zydus's argument that claim 1 of the '994 patent was invalid for lack of enablement because one of skill in the art would not be able to determine the average particle diameter using the coulter counter method of measurement without undue experimentation. Here, the Court found that because the specification identified laser diffraction as a viable measurement technique, one of ordinary skill in the art would know how to measure particle diameter, which was sufficient to show enablement. The Court noted, however, that if the district court had been correct in determining that the '994 patent required measuring the average particle diameter of each dissected agglomerate, the Court would have necessarily reached a different conclusion regarding enablement. Because the Court determined that deagglomeration was not required prior to particle size measurement, the Court concluded that the '994 patent could not be found invalid for lack of enablement.

Thus, the Court reversed the district court's claim construction ruling and finding of literal infringement but affirmed the judgment of no invalidity, and remanded for further proceedings.

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SJ of Noninfringement Vacated Where Record Was Insufficient to Provide Proper Claim Constructions

Abigail Lubow

Judges: Rader, Taranto (author), Chen

[Appealed from S.D. Tex., Judge Hughes]

In *Frans Nooren Afdichtingssystemen B.V. v. Stopaq Amcorr Inc.*, No. 13-1200 (Fed. Cir. Feb. 21, 2014), the Federal Circuit vacated a grant of SJ of noninfringement, concluding that the district court made errors in at least one underlying claim construction. The Court remanded the case for further proceedings.

Frans Nooren Afdichtingssystemen B.V. ("Nooren") owns U.S. Patent No. 5,898,044 ("the '044 patent"), which "discloses a composition used for insulating and protecting substrates . . . from corrosion, water ingress, and mechanical stresses." Slip op. at 2. Independent claim 1 recites "[a] shaped article comprising . . . *a filler comprising a plurality of fractions each comprising different size particles, and wherein said different fractions have different particle size distributions*." *Id.* (with emphasis denoting the "filler/fractions limitation"). The '044 patent is licensed exclusively to the Dutch company, Stopaq B.V. The Dutch company, Kleiss & Co. B.V. ("Kleiss"), manufactures products that prevent corrosion and protect against leaks: ViscoWrap, which contains a mixture of polybutene, polypropylene, and aluminum trihydrate; and EZ Wrap and Hippo Patch, which contain a mixture of polybutene, polypropylene, and calcium carbonate.

Kleiss and its U.S. distributors, Amcorr Products and Services, Inc. and Dolphin Sealants LLC (collectively "Amcorr"), filed a DJ action for noninfringement in the Netherlands against Nooren. One week later, Nooren brought an action for infringement against Amcorr in the U.S. District Court for the Southern District of Texas. Amcorr asserted affirmative defenses of noninfringement and invalidity.

The parties filed cross-motions for SJ on the issue of infringement, and the district court granted Amcorr's motion, finding noninfringement as a matter of law. In doing so, the district court "adopt[ed] both of Amcorr's grounds for concluding that polypropylene cannot help meet the [filler/fractions] limitation," and "adopt[ed] Amcorr's position that neither the aluminum trihydrate nor the calcium carbonate meets the specific requirements for a plurality of 'fractions.'" *Id.* at 5-6. Nooren appealed.

"There has been insufficient exploration in the record, both here and in the district court, of too many questions of apparent relevance to identifying a proper construction of the limitation, which requires, among other things, that the construction itself supply a 'meaningfully precise claim scope.'" Slip op. at 11-12 (quoting *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008); citing *MeadWestVaco Corp. v. Rexam Beauty &*

***Closures, Inc.*, 731 F.3d 1258, 1270 n.8 (Fed. Cir. 2013)).**

On appeal, the Federal Circuit noted that the district court's principal ground for finding that polypropylene in the accused products played no role in meeting the filler/fractions limitation was the district court's construction that "a filler" in the '044 patent could contain only "one material." *Id.* at 6. The Court disagreed with the district court's construction, reasoning that nothing in the term's customary usage or the specification excluded "a filler" from being a mixture of two different "materials." *Id.* at 7. The Court disagreed with the district court's reliance on the prosecution history, finding that there was no clear prosecution-history narrowing of "a filler" to a single material where the applicants never stated or implied an exclusion of dual-material fillers. The Court also disagreed with Amcorr's claim-differentiation argument, reasoning that there was no persuasive connection between the claim differences and the number of materials that can be "a filler."

The Court then turned to the district court's second ground for finding that polypropylene in the accused products played no role in meeting the filler/fractions limitation, namely, the district court's conclusion that the polypropylene in Amcorr's products was not a filler at all. The Court found that the district court lacked sufficient support for this finding, but also was not persuaded by Nooren's competing construction of "a filler." Instead, the Court held that "a filler" should be accorded the dictionary definition proposed by Amcorr that appeared to be uncontroverted by Nooren and that appeared to fit the '044 patent. The Court noted that the district court did not recite this construction, and that the experts disagreed about whether polypropylene in the accused products was serving as a filler. The Court stated that it was thus "not prepared to affirm the district court's conclusion that, as a matter of law, the polypropylene in the accused products is not serving as a filler." *Id.* at 10.

The Court stated it would not make a determination of infringement because "[t]here has been insufficient exploration in the record, both here and in the district court, of too many questions of apparent relevance to identifying a proper construction of the limitation, which requires, among other things, that the construction itself supply a 'meaningfully precise claim scope.'" *Id.* at 11-12 (quoting *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008); citing *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1270 n.8 (Fed. Cir. 2013)). The Court reasoned, for example, that the district court's reliance on certain graphical representations for claim construction was problematic because there were a number of graphs used and the terms used in describing the graphs raised questions of precision, which could raise an indefiniteness problem. The Court noted that it did "not mean to be exhaustive or to suggest the absence of solutions," but rather was "identifying at least some of the problems that require attention in a more focused and systematic claim-construction analysis than the parties and the record currently supply." *Id.* at 18. The Court thus vacated the district court's grant of SJ of noninfringement and remanded for further proceedings.

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En Banc Federal Circuit Confirms De Novo Appellate Review of Claim Construction

Adam S. Boger

Judges: Rader, Newman (author), Lourie (concurring), Dyk, Prost, Moore, O'Malley (dissenting), Reyna, Wallach, Taranto

[Appealed from N.D. Tex., Judge O'Connor]

In *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, No. 12-1014 (Fed. Cir. Feb. 21, 2014) (en banc), the Federal Circuit en banc confirmed *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc), that claim construction is purely a matter of law subject to de novo appellate review.

Lighting Ballast Control LLC ("Lighting Ballast") asserted infringement of U.S. Patent No. 5,436,529, which relates to electric circuits used in fluorescent lighting. The district court construed the claim term "voltage source means" not as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6, but as corresponding to a class of structures. The district court then entered judgment for Lighting Ballast following a jury trial. On appeal, a panel of the Federal Circuit reviewed the district court's claim construction without deference, holding that the term "voltage source means" invoked means-plus-function claiming and was invalid for indefiniteness because the specification disclosed no corresponding structure. The Court then granted rehearing en banc to reconsider the standard of appellate review of claim construction.

In a split decision, a majority of the en banc Federal Circuit applied the principles of stare decisis and confirmed the *Cybor* standard of de novo review of claim construction as a matter of law. The Court first characterized the three general positions expressed by the parties and amici: (1) abandonment of the *Cybor* standard for deferential review of claim construction as a question of fact; (2) adoption of a hybrid-review standard with deferential review of the factual aspects of claim construction but with the ultimate construction a legal conclusion subject to de novo review; and (3) affirmance of the *Cybor* standard of de novo review. The Court next considered the principles of stare decisis, explaining that overturning *Cybor* required more than controversy regarding the prior standard. Rather, according to the Court, a departure from precedent may be appropriate when subsequent cases have undermined its doctrinal underpinnings, when the precedent has proved unworkable, or when a considerable body of new experience requires changing the law.

Applying these principles, the Federal Circuit held that the proponents of overruling *Cybor* had not met the demanding standards of the doctrine of stare decisis. The Court first concluded that no subsequent developments from the Supreme Court, Congress, or the Court had undermined the reasoning of *Cybor*. The Court also concluded that fifteen years of experience had demonstrated the ready workability of the *Cybor* standard. Reversing or modifying this standard, the Court explained, could decrease workability and increase litigation burdens by adding a new and uncertain inquiry given that no one, including the

dissent, had proposed a workable replacement standard. Moreover, according to the Court, a more deferential review standard would neither be more likely to achieve the correct claim construction nor affect a large number of claim construction disputes, because claim construction is a legal standard of the scope of the patent right, which does not turn on witness credibility and is not transformed into a matter of fact by reliance on extrinsic evidence. In fact, the Court reasoned, given the increased frequency with which the same patent is asserted in different forums against different defendants, giving deference to a district court's claim construction might prevent the uniform treatment of a given patent and result in the forum shopping the Federal Circuit was created to avoid. The Court thus concluded that "there is neither 'grave necessity' nor 'special justification' for departing from *Cybor*." Slip op. at 26.

"After fifteen years of experience with *Cybor*, we conclude that the court should retain plenary review of claim construction, thereby providing national uniformity, consistency, and finality to the meaning and scope of patent claims." Slip op. at 7.

The Federal Circuit then responded to arguments made by the dissent. The Court first remarked that contrary to the dissent's statement that a substantial proportion of the legal community believed *Cybor* to have been wrongly decided, all of the technology-industry amicus briefs supported retaining the existing standard of review. The Court next commented that the dissent offered no superior alternative to de novo review; failed to explain the benefits of abandoning de novo review, with its attendant benefit of intrajurisdictional certainty; and downplayed the gravity of overturning previous en banc decisions in the absence of intervening Supreme Court or legislative action. The Court also rejected the dissent's reliance on Fed. R. Civ. P. 52(a)(6), which dictates clear-error review of district courts' factual findings, explaining that the rule does not determine what is properly considered a question of fact. Finally, the Court contested the evidentiary basis for the dissent's argument that the *Cybor* standard has produced a high reversal rate, and thus added considerable uncertainty and expense to patent litigation, citing data that reversal rates for claim construction match those of other patent-related issues and that there has been a decline in the appeal rate of district court patent cases.

Accordingly, the Federal Circuit confirmed on the basis of stare decisis the *Cybor* standard of de novo appellate review of claim construction as a matter of law.

Judge Lourie concurred, joining the majority opinion but writing separately to note additional reasons why retaining *Cybor* was wise. First and foremost, according to Judge Lourie, the Supreme Court held that claim construction is a question for the court, not the jury. Equally important to Judge Lourie was the goal of uniformity in interpreting patent claims, a goal consistent with the purpose of creating the Court and a goal that would be undermined if deference to a district court's determination led to conflicting claim constructions in different cases. In Judge Lourie's view, claim construction is not a process that normally involves historical facts, but rather primarily involves reading the patent's written description and prosecution history, a process analogous to the interpretation of other legal instruments, such as contracts and statutes. Moreover, Judge Lourie explained, it was incorrect that the Court did not give any deference to a district court's claim construction since, when asked to construe the claims, the Court notes and considers the district court's construction, and when the Court disagrees, "it is not without a degree of informal deference." Lourie Concurrence at 5. Thus, according to Judge Lourie, splitting claim construction into legal and factual issues would threaten uniformity achieved by intensive appellate review and create a complication that ordinarily would not make a difference given proper informal deference.

Judge O'Malley dissented, joined by Chief Judge Rader and Judges Reyna and Wallach, and disagreed that stare decisis justified adhering to the *Cybor* standard. Judge O'Malley argued that reversing *Cybor* would not upset expectations in the legal community as no one believes its validity to be settled, pointing to the debate over *Cybor* within the Court and among litigants, practitioners, and academics. Moreover, according to Judge O'Malley, *Cybor* misapprehends the Supreme Court's decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), which acknowledged the factual aspects of claim

construction, and ignores the realities of the claim construction process, which involves factual issues as acknowledged by both parties, the PTO, and most amici. Judge O'Malley also argued that *Cybor* contravenes Rule 52(a)(6), which instructs the Court that findings of fact must not be set aside unless clearly erroneous. Finally, Judge O'Malley argued that overruling *Cybor* is justified because of the undesired consequences of refusing to acknowledge the factual aspect of claim construction: *Cybor* has made the claim construction process less transparent, accurate, predictable, and efficient, thus undermining the very interests promoted by stare decisis; has increased the cost of litigation by creating incentives to appeal and discouraging settlements; and has failed to promote uniformity or predictability given claim construction's fact-specific nature. Thus, according to Judge O'Malley, while the ultimate question of claim meaning should remain subject to de novo review, the Court should defer to the district court's factual findings needed to resolve claim construction disputes unless clearly erroneous.

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The Structural Definition of Species Properties May Provide Adequate Written Description of a Genus

Richard M. Hanna

Judges: O'Malley, Wallach, Taranto (author)

[Appealed from D. Del., Judge Andrews]

In *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, Nos. 13-1593, -1594, -1595, -1598 (Fed. Cir. Feb. 24, 2014), the Federal Circuit affirmed the district court's rejection of the written-description challenge to U.S. Patent No. 5,565,467 ("the '467 patent").

GlaxoSmithKline LLC ("GSK") is the holder of the '467 patent, which includes claims directed to the chemical compound dutasteride or a "pharmaceutically acceptable solvate thereof." Slip op. at 3 (citation omitted). GSK markets Avodart® and Jalyn™, which contain dutasteride. Banner Pharmacaps, Inc., Impax Laboratories, Inc., Roxane Laboratories, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., and Watson Laboratories, Inc.–Florida (collectively "Defendants"), each filed at least one ANDA to market generic versions of Avodart® and Jalyn™. GSK, in turn, sued for infringement.

At trial, Defendants stipulated to infringement but challenged the validity of the '467 patent on the grounds of anticipation, lack of utility, lack of enablement, and inadequacy of written description. Defendants' arguments centered on the claim term "pharmaceutically acceptable solvate," more specifically, "solvate." The parties, during trial, agreed that solvates are molecules that either consist of solute molecules and solvent molecules or result from a solution of the solute and solvent molecules. The parties further agreed that solvate complexes may be crystalline. The parties, however, disagreed as to whether, in the context of the '467 patent, solvates *must* be crystalline. Defendants urged a narrow construction, but the district court construed the claims more broadly to include both crystalline and noncrystalline structures. Defendants asserted that the written description of the '467 patent failed under either construction of the term "solvate." The district court disagreed, finding that "[t]here is no reason why a person skilled in the art would not credit a patentee with possession of a solvate merely because the patentee did not disclose solvates formed by each solvation process." Slip op. at 7 (alteration in original) (quoting *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, No. 11-CV-046, 2013 WL 4082232, at *5 (D. Del. Aug. 9, 2013)). After a bench trial, the district court upheld the validity of the '467 patent.

"The claim term and its corresponding description, however broad, identify certain structures produced by certain processes. We have not required more for an adequate written description that matches claim scope." Slip op. at 11.

On appeal, Defendants presented a single issue: "whether, under what is now 35 U.S.C. § 112(a), the written description of the '467 patent adequately supports the claims to 'solvates' of dutasteride."

Id. at 7-8. The Federal Circuit rejected Defendants' challenge because, "[u]nder either the district court's claim construction or Defendants' claim construction, the claim term 'solvate' refers to a molecular complex defined by structure and by the process of creating it, not by what the molecule does." *Id.* at 8. The Court explained that, under *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, "adequate written description requires a precise definition, such as by *structure*, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials." *Id.* at 10 (quoting *Ariad*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc)). Here, the written description described the same class by identifying a particular structure obtained by particular processes. Accordingly, the Court affirmed the district court's finding because, regardless of which construction was adopted, the term "solvate" involved no performance property and thus raised no issue of insufficient description to support such a property.

The Court differentiated this case from those cited by Defendants by emphasizing the structural nature of the claim term "solvate." The Court stated that "[c]ritically, moreover, the claim term at issue, 'solvate,' is not functional: to be a 'solvate,' a compound need not produce a desired result or otherwise perform a certain function." *Id.* at 11. In the precedential cases cited by Defendants in support of their position, the Court explained, the disputed claim terms were of a functional nature, claiming a particular performance property. Such claims have the "fundamental difficulty" of potentially claiming future inventions and may therefore exceed the scope of the written description. *Id.* at 12. In contrast, the claims of the '467 patent, being structural in nature, the Court reasoned, cannot exceed the scope of the written description, as the structure is set forth in the specification.

Accordingly, the Federal Circuit affirmed the district court's rejection of Defendants' written-description challenge to the validity of the '467 patent.

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Ambiguity as to Whether a Patentee Intended to Depart from the Ordinary Meaning of a Term Does Not Indicate a Clear Intent to Depart

Ming W. Choy

Judges: Moore, Schall (author), Reyna

[Appealed from D. Del., Chief Judge Sleet]

In *Starhome GmbH v. AT&T Mobility LLC*, No. 12-1694 (Fed. Cir. Feb. 24, 2014), the Federal Circuit affirmed the district court's SJ of noninfringement.

Plaintiff Starhome GmbH ("Starhome") sued Defendants AT&T Mobility LLC, Roamware, Inc., and T-Mobile USA, Inc. (collectively "AT&T") for infringement of U.S. Patent No. 6,920,487 ("the '487 patent").
The '487 patent is directed to a system and method of improving the functionality of phone services for users in a roaming telephone network by use of an "intelligent gateway" that assists in translating a dialing sequence while in the roaming network. Starhome alleged that AT&T's network platform, which runs applications that allow mobile-network operators to translate numbers dialed by roaming cell-phone users, infringed the '487 patent. AT&T's network platform does not connect to an external packet-switch network or other external network.

After a *Markman* hearing, the district court issued its claim construction order, where the district court found that the word "gateway" in the claims has a well-known technical meaning in the telecommunications industry, and that Starhome did not clearly redefine the term in the '487 patent. The district court found that the word "gateway" refers to a device that connects two or more networks. Finding that AT&T set forth a compelling argument of noninfringement based on the construction of "intelligent gateway," the district court granted AT&T's request for SJ of noninfringement. Starhome appealed.

"At best, Figure 2 inserts ambiguity as to whether the patentees intended to depart from the ordinary meaning of 'intelligent gateway.' But such ambiguity does not rise to the level of the clear intent our case law requires." Slip op. at 12-13 (citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002)).

On appeal, the Federal Circuit affirmed the district court's construction of the claim term "intelligent gateway" and judgment of noninfringement. The Court first noted that, as a general rule, the words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history. The Court noted that there are only two exceptions to this general rule: (1) when the patentee sets out a definition and acts as his own lexicographer; or (2) when the patentee disavows the full scope of a claim term either in the

specification or during prosecution. The Court also noted that dictionaries and treatises are often useful for claim construction, and can be used as long as the dictionary definition does not contradict with any definition found or ascertained by the patent documents.

The Court then considered the district court's construction of "gateway." The Court noted that the term "gateway" had a well-understood meaning in the art at the time the patentees filed the application that led to the '487 patent, and cited technical dictionaries to show that one of ordinary skill in the art would have understood "gateway" to be a connection between different networks. And in the context of the '487 patent, the Court agreed with AT&T that the ordinary meaning of "gateway," which refers to a connection between different networks, should control. The Court held that the usage of the claimed "intelligent gateway" term in the specification does not alter the ordinary meaning of "gateway" as understood by one of ordinary skill in the art, since the gateway is intelligent by virtue of the fact that it includes a database of information and is adapted to perform numerous functions.

The Court also held that the ordinary meaning is consistent with the specification, which describes a global packet-switch network connecting mobile networks via intelligent gateways. The Court also held that the figure in the '487 patent showing a gateway connected solely to an internal network does not constitute a separate embodiment, as the specification explains that the figure is a simplified drawing of another embodiment. The Court noted that even if that figure inserted ambiguity as to whether Starhome intended to have the meaning of the word "intelligent gateway" depart from its ordinary meaning, the ambiguity does not rise to the level of express intent to impart a novel meaning to "intelligent gateway."

The Court also found that the doctrine of claim differentiation is not controlling in this case. As the Court noted, claim differentiation is "a rule of thumb that does not trump the clear import of the specification." Slip op. at 13 (quoting *Edwards Lifesciences LLC v. Cook, Inc.*, 582 F.3d 1322, 1332 (Fed. Cir. 2009)). The Court noted that the district court's construction of "intelligent gateway" does not create inconsistency under the doctrine of claim differentiation because claims 1 and 47 of the '487 patent, which recite a gateway connected to a packet-switch network, are only narrower in scope than asserted claims 10 and 40. The Court found that such a construction neither imports limitations from one claim to another nor renders any claims redundant.

Accordingly, the Court affirmed the district court's claim construction, as well as the district court's SJ of noninfringement.

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Looking Ahead

On February 26, 2014, the U.S. Supreme Court heard oral argument in two patent cases involving attorneys' fees under 35 U.S.C. § 285. First, the Supreme Court heard arguments in *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, No. 12-1184, regarding the Federal Circuit's affirmation of a denial of fees due to the Court not finding the case "exceptional" under Federal Circuit precedent. Petitioner Octane Fitness, LLC appealed the Federal Circuit's ruling, presenting arguments against the Federal Circuit's requirement that a case be "objectively baseless" to be eligible for a fee award. Second, the Supreme Court heard arguments in *Highmark Inc. v. Allcare Health Management Systems, Inc.*, No. 12-1163, regarding the Federal Circuit's reversal of the district court's finding that certain of Allcare Health Management Systems, Inc.'s claims were objectively baseless, having reviewed the district court's determination de novo. Petitioner Highmark Inc. appealed the Federal Circuit's ruling, arguing that a unitary "abuse of discretion" standard of review should be used for all § 285 determinations.

The Supreme Court is expected to rule on the cases by the end of this year's term in June 2014.

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Spotlight Info

In *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, No. 12-1014 (Fed. Cir. Feb. 21, 2014) (en banc), the Federal Circuit en banc confirmed the review standard for claim construction established in *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc), that claim construction is purely a matter of law subject to de novo appellate review. Relying on stare decisis, the Court concluded that subsequent cases and experience had not undermined *Cybor*'s doctrinal underpinnings and that fifteen years of experience had demonstrated the ready workability of the *Cybor* standard. Judge Lourie wrote a separate concurrence, noting that the Court's review of district courts' claim construction was not without a degree of informal deference. Judge O'Malley, joined by three other judges, dissented, arguing that stare decisis did not justify adherence to *Cybor*, which misapprehended Supreme Court precedent; ignored the factual nature of the claim construction process; contravened Fed. R. Civ. P. 52(a)(6); and had made claim construction less transparent, accurate, predictable, and efficient, thus undermining the very interests promoted by stare decisis. See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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