

Last month at

# The Federal Circuit



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**COURT FINDS PAROXETINE PATENT INVALID BASED ON NEW PRIOR ART**

After en banc Court vacates prior ruling of invalidity based on public use, panel issues new decision of invalidity based on prior art patent. *SmithKline Beecham Corp. v. Apotex Corp.*, No. 03-1285 (Fed. Cir. Apr. 8, 2005) .....1

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EDITED BY | VINCE KOVALICK

## Court Finds Paroxetine Patent Invalid Based on New Prior Art

Jennifer S. Swan

[Judges: Rader (author), Bryson, and Gajarsa]

In *SmithKline Beecham Corp. v. Apotex Corp.*, No. 03-1285 (Fed. Cir. Apr. 8, 2005), the Federal Circuit, sitting en banc, vacated the prior panel's decision, *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004), that claim 1 of U.S. Patent No. 4,721,723 ("the '723 patent") was invalid under the "public use" bar of 35 U.S.C. § 102(b). The Court then remanded the case back to the panel for further proceedings.

In a new decision, *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005), issued the same day, the panel again held that Apotex Corporation ("Apotex") infringed claim 1, which recites a "crystalline paroxetine hydrochloride hemihydrate." The panel found that claim 1 covers any amount of paroxetine hydrochloride hemihydrate without limitation and that the scope of this claim would be clear to those of skill in the art. The panel rejected the district court's indefiniteness findings, stating that "the test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." The panel adopted the district court's factual finding that Apotex's paroxetine hydrochloride anhydrate would contain paroxetine hydrochloride hemihydrate and, thus, found that under the correct claim construction, Apotex would infringe claim 1.

The Court, however, also held claim 1 of the '723 patent invalid, but this time on a different ground than public use.

Following the en banc decision that vacated the public-use determination, the Federal Circuit reversed the district court and held that claim 1 of the '723 patent was inherently anticipated by U.S. Patent No. 4,007,196 ("the '196 patent"). Apotex had not appealed this decision to the Federal Circuit. Specifically, in its prior public-use opinion, the panel had noted that "the district court . . . determined that Apotex did not present clear and convincing evidence of inherent anticipation . . . . Apotex does not appeal that Ruling." *SB v. Apotex*, 365 F.3d at 1315.

Nevertheless, in a split decision, the majority panel *sua sponte* reversed the district court and held the claim invalid for inherent anticipation over the '196 patent. The '196 patent does not disclose paroxetine hydrochloride, but discloses a maleate salt form of paroxetine. Although there was no evidence in the record that before the preparation of hemihydrate by the named inventors, anyone had ever practiced the '196 patent and obtained hemihydrate, and no evidence that anyone had ever recognized the existence of hemihydrate in the prior art, the majority held that the '196 patent necessarily produced undetectable amounts of paroxetine hydrochloride hemihydrate. Thus, the majority invalidated claim 1 under 35 U.S.C. § 102(b).

Judge Gajarsa filed a separate opinion concurring in the judgment. Judge Gajarsa would have held the '723 patent infringed by Apotex, but claim 1 invalid under 35 U.S.C. § 101.

Judge Newman dissented from the panel's inherency holding, stating that it "contravenes long-established precedent." *SmithKline Beecham Corp. v. Apotex*, 403 F.3d 1328, 1330 (Fed. Cir. 2005). Judge Newman stated that there was no evidence that PHC hemihydrate existed at the time the '196 patent was filed. She stated that the district court's finding that the PHC hemihydrates had not been pro-

duced in 1975 was not shown to be clearly erroneous. As Judge Newman stated, inherent anticipation requires that the identical invention was known or its existence would have reasonably been known to a person of ordinary skill—not that it might have lain hidden in miniscule amounts, undetected, unsuspected, or unknown.

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## Dismissal of District Court Action with Prejudice Was Abuse of Discretion

*Alan A. Wright*

**[Judges: Linn (author), Michel, and Gajarsa]**

In *Bowling v. Hasbro, Inc.*, No. 04-1364 (Fed. Cir. Apr. 11, 2005), the Federal Circuit reversed a district court's dismissal with prejudice of Plaintiff's patent-infringement suit. Michael Bowling had sued Hasbro, Inc. ("Hasbro") in the U.S. District Court for the District of Arizona on September 16, 2003. However, Bowling did not serve Hasbro with the Complaint. On January 26, 2004, the district court issued an order to show cause, requiring Bowling to explain why his suit should not be dismissed for failure to serve Hasbro within the 120 days provided in Fed. R. Civ. P. 4(m). After Bowling failed to respond to the order, the district court dismissed the action with prejudice.

The Federal Circuit reversed the district court's dismissal, stating that the district court had abused its discretion. Applying regional circuit law, the Federal Circuit considered the five factors that the Ninth Circuit considers in deciding whether dismissal is appropriate: (1) the public's interest in expeditious resolution of litigation; (2) the court's need to manage its docket; (3) the risk of prejudice to defendant; (4) the availability of less drastic

alternatives; and (5) the public policy of disposing of the case on its merits. The Federal Circuit noted that the district court had weighed these five factors in deciding to dismiss Bowling's case with prejudice. However, the Court ultimately held that Ninth Circuit law generally emphasized the notions of warning and consideration of less drastic alternatives than dismissal with prejudice. Noting that Rule 4(m), which the district court relied upon as a predicate for dismissal, does not authorize dismissal with prejudice, the Federal Circuit held that the district court had abused its discretion. Because the district court had failed to provide Bowling with sufficient notice that his suit would face the extreme result of dismissal with prejudice, and because Bowling's behavior was deemed not overly egregious, the Federal Circuit reversed the dismissal and remanded the case.

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## Lack of Detail in Claim-Construction Analysis and Infringement Findings Results in Remand

*Christopher S. Schultz*

**[Judges: Rader (author), Michel, and Prost]**

In *Nazomi Communications, Inc. v. ARM Holdings, PLC*, No. 04-1101 (Fed. Cir. Apr. 11, 2005), the Federal Circuit vacated and remanded the district court's grant of SJ of noninfringement of U.S. Patent No. 6,332,215 ("the '215 patent") due to insufficiently detailed claim-construction analysis and noninfringement findings by the district court.

The '215 patent is directed to a computer-hardware accelerator that translates stack-based Java bytecode instructions into register-based instructions that

are usable by a register-based CPU. Claim 1 includes a “hardware unit adapted to convert stack-based instructions into register-based instructions.” The parties disputed the meaning of the term “instructions” in this claim element. At the district court, the Plaintiff patent owner, Nazomi Communications, Inc. (“Nazomi”), proposed that the term meant a command that specifies or causes performance of an operation or function. The Defendants, ARM Holdings, PLC, ARM Limited, and ARM, Inc. (collectively “ARM”), proposed a narrower definition, including that the instructions be “provided to the processor at its input and thus be recognizable to the decoder.” ARM further sought to limit the term to exclude “control signals,” which are the signals generated by the processor’s decoder that control downstream hardware.

The district court ruled that the “hardware unit or subunit that converts stack-based instructions into the register-based instructions [do so] prior to the processing of those instructions by the processor in the so-called ‘decode stage.’” Under this construction, without analyzing the accused product, the district court concluded that ARM’s device did not infringe literally or under the DOE, and granted ARM’s motion for SJ of noninfringement.

The Federal Circuit concluded that the district court, at best, glossed over the intrinsic evidence and improperly focused on reading the claims to preserve their validity. While acknowledging the rule that, if practicable, claims are to be read to preserve their validity, the Court stated that the claims must first be properly construed, “[o]therwise the construing court has put the validity cart before the claim construction horse.” *Nazomi*, slip op. at 7.

The Federal Circuit then reviewed its litany of claim-construction inquiries to assist the district court in its claim-construction analysis of the term “instruc-

tions,” including the intrinsic evidence, expert testimony, the prior art, and claim differentiation.

The Federal Circuit also found the district court’s infringement analysis insufficient for review due to a lack of findings of fact on the nature of the accused device and based on a “circular” infringement analysis that improperly strived to preserve validity. Further, because the district court had construed the claims differently than the parties, the record did not include evidence that the accused product included each feature of the construed claims. Accordingly, the Federal Circuit vacated and remanded to the district court for a detailed claim-construction analysis and for factual findings on the infringement issue.

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## Claim Construction Affirmed, but Remand on Infringement

*Ningling Wang*

[Judges: Gajarsa (author), Newman, and Clevenger]

In *Rhodia Chimie v. PPG Industries Inc.*, No. 04-1246 (Fed. Cir. Apr. 11, 2005), the Federal Circuit affirmed-in-part and reversed-in-part the district court’s SJ in favor of PPG Industries, Inc. (“PPG”), and remanded on infringement because the evidence before the court created a genuine issue of material fact regarding one of PPG’s accused products.

Rhodia Chimie and Rhodia Inc. (collectively “Rhodia”) are the assignees of U.S. Patent No. 6,013,234 (“the ‘234 patent”), which discloses and claims certain essentially spheroidal precipitated silica particulates and processes of manufacturing those particulates. The sole claim at issue contains the disputed terms “dust-free and non-dusting” and “atomized precipitated silica particulate.” Rhodia identified three silica products made by PPG, i.e.,

Hi-Sil SC60M, SC72, and SC72C, that allegedly infringe claim 1 of the '234 patent, and sued PPG for willful infringement.

The Federal Circuit affirmed the district court's construction of the disputed term "dust-free and non-dusting" to mean "a level of dust formation associated with the silica particulates of the '234 patent, as measured in percentage weight according to DIN 53 583, that has a fines content value of less than or equal to 13 and weight loss by abrasion value less than or equal to 0.5." "DIN 53 583" is an industrial standard that provides a test for measuring the fines content and weight loss by abrasion of palletized carbon black used as fillers in the rubber-processing industry (the "DIN test").

The Federal Circuit reasoned that the term "dust-free and non-dusting" could not be read literally to mean that the invention creates no silica dust at all, as advocated by PPG, because the test results disclosed in the written description indicate that the invention itself produces some dust, but less dust than the prior art. The Court also noted that the term "dust-free and non-dusting" could not be construed to mean that the level of dust "is very low when compared to other silica forms," as advocated by Rhodia, because such a definition is "a relative phrase," which can only be understood in comparison to the prior art. Instead, the Federal Circuit looked at the written description of the '234 patent, specifically, the ten examples disclosed therein, and determined that referring to the DIN test in defining the term "dust-free and non-dusting" reconciles the ambiguous claim language with the inventor's disclosure.

Rhodia challenged this claim construction on the ground that the DIN test is not the only method by which to assess the amount of dust produced by the invention in comparison to the prior art. Rhodia argued that the pour test disclosed

in the specification could also be used to assess the amount of dust, relying on the statements made during the prosecution of the patent showing that the pictures of the pour test were cited as evidence of the nondusting and free-flowing properties. However, the Federal Circuit held that because neither the claims nor the written description teaches the use of the pour test to determine the level of dust production claimed by the invention, the statements made during the prosecution of the '234 patent could not serve to fill that gap.

The Federal Circuit also affirmed the district court's construction of the disputed term "atomized precipitated silica particulates" to mean "that a pulverized slurry of precipitated silica is spray dried using a liquid pressure nozzle as an atomizer to form the claimed silica particulates," in view of the prosecution history, where Rhodia distinguished the prior art by emphasizing that its claimed silica particulates could be obtained only by applying liquid-pressure nozzle sprayers to a pulverized slurry.

Rhodia further challenged the district court's decision of no literal infringement on two grounds: (1) the district court abused its discretion in excluding Rhodia's DIN testing evidence on PPG's accused products; and (2) even without the excluded DIN test results, the evidence provided by PPG showing that PPG's own DIN testing results for one of the accused products, i.e., SC60M, fall within the range established by the district court's claim construction raised a genuine issue of material fact as to literal infringement.

The Federal Circuit held that the district court did not abuse its discretion in excluding Rhodia's DIN testing results under Third Circuit law, because it was unreasonable for Rhodia to delay investigation into DIN testing until after the issuance of the claim-construction opinion.

As to Rhodia's second evidentiary ground in challenging the district court's decision of no literal infringement, PPG argued that the evidence on its DIN testing results for SC60M was irrelevant because the results were produced prior to the issuance of the '234 patent and Rhodia produced no evidence linking the sample tested to PPG's postissuance commercial practices. The Federal Circuit rejected PPG's arguments and reemphasized that evidence regarding preissuance activities may be relevant to establishing that postissuance products constitute infringement. Therefore, the Court concluded that the evidence on PPG's own DIN testing results for SC60M created a genuine issue of material fact as to whether the postissuance form of SC60M literally infringes the '234 patent.

Finally, the Federal Circuit affirmed the district court's decision of noninfringement under the DOE because of prosecution history estoppel, as Rhodia made narrowing amendments in the prosecution of the patent to overcome prior art rejections.

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## Satellite Patent Not Invalid

*Vince Kovalick*

**[Judges: Newman (author), Michel, and Gajarsa]**

In *Space Systems/Loral, Inc. v. Lockheed Martin Corp.*, No. 04-1501 (Fed. Cir. Apr. 20, 2005), the Federal Circuit reversed a judgment that U.S. Patent No. 4,537,375 ("the '375 patent") is invalid for violating the written description requirement of 35 U.S.C. § 112. Space Systems/Loral, Inc. ("Loral") owns the '375 patent, which is directed to an improved method for maintaining the orientation and attitude of a satellite. To maintain a correct position in space, a satellite forms station-keeping maneuvers by firing its thrusters. The '375

patent is directed to a method of reducing fuel consumption during such station-keeping maneuvers. The claims of the '375 patent concern a two-step process, wherein the satellite conducts a first firing of the thrusters based on a correction estimated from historical data of prior station-keeping maneuvers (called the "prebias" step) and a second firing based on the actual remaining error in its position.

Loral brought suit against Lockheed Martin Corporation ("Lockheed") for infringement of claim 1. Lockheed moved for SJ of invalidity based on the written description requirement of 35 U.S.C. § 112, arguing that the specification does not adequately describe the second step in which the satellite calculates the position after the first firing and performs a second firing of the thrusters. The district court adopted Lockheed's position.

On appeal, the Federal Circuit disagreed with the district court's conclusion, noting that even Lockheed's own expert had conceded that the second step was shown in the specification. Although Lockheed criticized the expert's testimony as being conclusory, the Federal Circuit found that that expert's testimony was quite specific, pointing to specific circuitry of the figures. Accordingly, the Federal Circuit reversed the SJ of invalidity and remanded the case.

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## Whereby Clause Is an Effective Limitation

*Vince Kovalick*

**[Judges: Newman, Bryson, and Dyk (per curiam)]**

In *Hoffer v. Microsoft Corp.*, No. 04-1103 (Fed. Cir. Apr. 22, 2005), the Federal Circuit affirmed a judgment of noninfringement, but reversed a judgment of invalidity on the ground of indefiniteness

for U.S. Patent No. 5,799,151 (“the ‘151 patent”).

The ‘151 patent is directed to an apparatus and method by which remote users of computer terminals obtain data concerning economic activity from an index and interactively communicate concerning economic topics. The claim in question includes a whereby clause, which recites that a trade network supports users who are collectively able to concurrently engage in interactive-data messaging on topic boards. The patent holder, Steven Hoffer, argued that the district court had erred in holding that this whereby clause limited the claim, pointing out that the Federal Circuit had previously held that “a written clause in a method claim is not given weight when it simply expresses the intended result of a process set positively recited.” *Minton v. Nat’l Ass’n of Secs. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003). According to the Federal Circuit, however, when the whereby clause states a condition that is material to patentability, it cannot be ignored. The Court observed that, according to the specification, this whereby clause is not just an intended result of a process step but is part of the process itself and is described as an integral part of the inventive process. Accordingly, the Federal Circuit agreed with the district court’s claim construction of the whereby clause and affirmed the judgment of noninfringement.

Claim 22 as written is dependent from claim 38. However, there is no claim 38 in the issued patent. The district court held claim 22 invalid for indefiniteness based on this error. The Federal Circuit vacated that decision, however, concluding that the error in the dependence of claim 22 is apparent on the face of the printed patent and the correct antecedent claim is apparent from the prosecution history. The error arose through the normal prosecution of deleting and renum-

bering certain claims. The Examiner simply failed to correct the corresponding claim dependency. Although Mr. Hoffer later obtained a certificate of correction, the district court declined to accept it, deeming it late and concluding that the court was powerless to correct the error. The Federal Circuit ruled that absent evidence of culpability or intent to deceive, a patent should not be invalidated based on an obvious administrative error. When a harmless error in a patent is not subject to reasonable debate, it can be corrected by the district court.

Judge Newman concurred in the judgment, but wrote separately to express her concerns that the Court did not review the entire appealed claim construction.

## Specification Is Key to Claim Construction

*Daniel X. Yan*

**[Judges: Bryson (author), Newman, and Dyk]**

In *Nellcor Puritan Bennett, Inc. v. Masimo Corp.*, No. 04-1247 (Fed. Cir. Apr. 8, 2005), the Federal Circuit vacated a district court’s decision granting SJ of noninfringement, because the district court had erred in its claim construction.

Nellcor Puritan Bennett, Inc. (“Nellcor”) owns U.S. Patent No. 4,934,372 (“the ‘372 patent”), which covers a method and apparatus for determining the oxygen-saturation level in blood by processing the signals received from a pulse oximeter. Claim 1 of the ‘372 patent claims a method for calculating the amount of a blood constituent, in which the aperiodic information is “attenuated and filtered” from the composite signal.

On appeal, Nellcor first contended that the district court had erred in construing the phrase “attenuated and fil-

tered” to mean “reduced and removed.” The Federal Circuit agreed. Finding the ordinary dictionary meaning of the term “filtered” to be consistent with Nellcor’s proposed definition, the Federal Circuit focused its analysis on the specification of the ‘372 patent and observed that the process described in the ‘372 patent does not actually remove data. Rather, the invention covered by the ‘372 patent merely results in the suppression of aperiodic noise relative to the periodic signal. Therefore, the Court concluded that the term “attenuated and filtered” means constantly reducing the level of aperiodic signals, rather than removing unwanted data all together.

The Federal Circuit noted that the district court’s reliance on the ‘372 patent’s prosecution history to support its interpretation of the terms was misplaced because the district court had misconstrued the reasons for applicants’ amendments to the claims.

The Federal Circuit also agreed with Nellcor’s contention that the district court had erred in ruling that the claims require a calculation using the relative minimum only after formation of a composite signal. The Court determined that, based on one embodiment in the ‘372 patent specification, the relative minimum, or the zero frequency, is computed when the average value of the signal is determined. Since the average value of the signal is an essential component in the computation of the composite signal, calculation of the relative minimum necessarily occurs before the formation of the composite signal.

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**In Last month at The Federal Circuit**, certain terms, titles, and names of federal agencies that are frequently referred to in text, appear in abbreviated forms or as acronyms. These abbreviated forms and acronyms are listed below.

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	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 & Drug Administration
IDS	Information Disclosure Statement
IP	Intellectual Property
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SEC	Securities and Exchange Commission
SJ	Summary Judgment
SM	Special Master