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[Appealed from N.D. Cal., Judge Hamilton]

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Webinar: Recent Supreme Court and Federal Circuit Cases Affecting Patentable Subject Matter

September 4, 2013

Abbreviations

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 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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August 2013

Cancellation of Claims by the PTO During Reexamination Is Binding in Concurrent Infringement Litigation

David C. Reese

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

[Appealed from N.D. Cal., Judge Hamilton]

In *Fresenius USA, Inc. v. Baxter International, Inc.*, Nos. 12-1334, -1335 (Fed. Cir. July 2, 2013), the Federal Circuit vacated and remanded with instructions to dismiss the district court's judgment of noninvalidity and infringement, concluding that cancellation of asserted claims in a reexamination proceeding is given effect in pending infringement litigation.

Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter") own U.S. Patent No. 5,247,434 ("the '434 patent"), which covers hemodialysis machines with touchscreen interfaces. In 2003, Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") filed a DJ action against Baxter for invalidity and noninfringement of claims 26-31 of the '434 patent. Fresenius counterclaimed for infringement. In February 2007, the district court entered judgment against Fresenius, finding claims 26-31 infringed and not invalid. On appeal, both parties stipulated to infringement, but Fresenius argued that the '434 patent was invalid. In September 2009, the Federal Circuit affirmed the determination that claims 26-31 of the '434 patent were not invalid, but remanded to the district court to reconsider its postverdict damages.

While the district court litigation was pending, in 2005, Fresenius requested ex parte reexamination of claims 26-31 of the '434 patent. In December 2007, the PTO examiner completed the reexamination of the '434 patent and determined that claims 26-31 were invalid. In March 2010, the Board affirmed the examiner's decision. On May 17, 2012, the Federal Circuit affirmed the PTO's invalidity determination of claims 26-31 of the '434 patent. Meanwhile, on March 16, 2012, the district court entered final judgment against Fresenius. Both parties appealed, disputing the effect of the PTO's cancellation of claims 26-31 on the infringement litigation, as well as issues related to damages. The primary question for the appeal was therefore whether, under the reexamination statute, the cancellation of claims by the PTO was binding on pending district court infringement litigation.

"As with the reissue statute, the language and legislative history of the reexamination statute show that Congress expected reexamination to take place concurrent with litigation, and that cancellation of claims during reexamination would be binding in concurrent infringement litigation."
Slip op. at 16.

"No hint can be found in the legislative record for an expectation of

concurrent proceedings; no hint of an intent that a PTO reexamination decision would override a prior judicial decision rendered in either prior or concurrent litigation. There is no authority for the majority's creative revision of the historical record." Newman Dissent at 9.

On appeal, Fresenius argued that the PTO's cancellation of claims 26-31 of the '434 patent divested Baxter of a cause of action for infringement. In agreeing with Fresenius, the Federal Circuit first reviewed the history and scope of the PTO's reissue and reexamination authority, determining that, "[a]s with the reissue statute, the language and legislative history of the reexamination statute show that Congress expected reexamination to take place concurrent with litigation, and that cancellation of claims during reexamination would be binding in concurrent infringement litigation." Slip op. at 16. Moreover, the Court noted that "under either the reissue or reexamination statute, if the PTO confirms the original claim in identical form, a suit based on that claim may continue, but if the original claim is cancelled or amended to cure invalidity, the patentee's cause of action is extinguished and the suit fails." *Id.* at 17.

Baxter argued that the cancellation of claims 26-31 of the '434 patent in the reexamination proceeding should not have been given effect during the present litigation because the validity of the '434 patent and Fresenius's liability for infringement of the '434 patent had already been conclusively decided prior to cancellation of the claims during the reexamination proceeding. According to Baxter, the district court's 2007 judgment regarding the issues of validity and infringement was "final" and "binding" on the parties in this case, and therefore has res judicata effect within the present litigation.

While the Federal Circuit was cognizant that the district court had entered a judgment final for purposes of appeal in 2007, the Court nevertheless concluded that the judgment was not sufficiently final to preclude application of the intervening final judgment in the PTO reexamination proceedings. Referencing an earlier decision, the Court explained that to rise to the requisite level of "finality," the litigation "must be entirely concluded so that [the] cause of action [against the infringer] was merged into a final judgment . . . one that 'ends the litigation on the merits and leaves nothing for the court to do but execute the judgment.'" *Id.* at 20 (quoting *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1580 (1994) (alterations in original)). And, according to the Court, the remand in the present litigation to the district court to reconsider its postverdict damages did not end the controversy between the parties or leave "nothing for the court to do but execute the judgment." *Id*. Rather, the Court went on to specify several aspects of the district court's original judgment that were left unresolved, including, for example, royalties on infringing machines, royalties on related disposables, and injunctive relief.

The Court next rejected Baxter's argument that under *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211 (1995), allowing a PTO determination to control the outcome of pending litigation is unconstitutional, because it offends the separation of powers. In particular, the Court relied on language from *Plaut* recognizing that appellate courts "must apply the law in effect at the time it renders its decision." Slip op. at 27 (quoting *Thorpe v. Hous. Auth. of the City of Durham*, 393 U.S. 268, 281 (1969)). The Court explained that its decision was fully consistent with this duty since it gave effect to the PTO's cancellation of claims asserted while the infringement litigation was still pending on appeal.

Accordingly, the Federal Circuit vacated and remanded with instructions to dismiss the district court's judgment of noninvalidity and infringement, since the asserted claims were cancelled by the PTO during a pending reexamination proceeding.

Judge Newman dissented on multiple grounds. First, Judge Newman opined that the holding violated the constitutional framework, which requires that "when there has been a prior judicial determination of the issue of patent validity, the conclusiveness of judicial rulings resolves the determination." Newman Dissent at 4. According to Judge Newman, "when the issue of validity of the claims has already been resolved in litigation, subsequent redetermination by the PTO is directly violative of the structure of government." *Id.* at 5. Judge Newman stressed that the reexamination statute fails to provide that a

decision in a PTO reexamination proceeding will override a judicial decision. Further, Judge Newman reasoned that if such were indeed to be the case, "it is inconceivable that no one would have mentioned it in the legislative process." *Id.* at 10.

Second, Judge Newman refuted the panel majority's "finality" construct and holding. Specifically, Judge Newman disagreed with the panel majority that the Court's 2009 judgment was not final because the judgment included a remand to the district court to assess postjudgment damages. Rather, Judge Newman noted that all of the issues on appeal were finally adjudicated by the Court, and that the remand only authorized the district court to determine postjudgment royalties. According to Judge Newman, "[t]he remand had no relation to any issue in reexamination; validity had been finally resolved in the courts." *Id.* at 15. Therefore, Judge Newman concluded that the judgment of validity should be binding on the courts, the parties, and the PTO.

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Board Decisions in Cases Where the Facts Are Largely Undisputed May Not Be Subject to a Substantial Evidence Standard of Review

Jose M. Recio

Judges: Dyk, Bryson (author), Wallach
[Appealed from Board]

In *Smith & Nephew, Inc. v. Rea*, No. 12-1343 (Fed. Cir. July 9, 2013), the Federal Circuit reversed the Board's obviousness decision holding that certain claims of U.S. Patent No. 7,128,744 ("the '744 patent") would not have been obvious.

The '744 patent claims priority to a provisional application filed on September 13, 1999, and is owned by Synthes (U.S.A.) ("Synthes"), a medical device company. The '744 patent is directed to a plate system for repairing bone fractures. The system is attached to fractured bones by bone anchors or screws inserted through holes in a plate and then into the bone. The system includes a shaft portion with anchor holes and a head portion with anchor holes that are conically tapered from the top surface to the bottom surface. The '744 patent also describes two types of prior art screws. The first type is compression or nonlocking screws with threaded shafts but unthreaded heads that typically pass through unthreaded holes. Compression or nonlocking screws draw the bone and plate together for quicker healing. The second type is locking screws with threaded shafts and threaded heads that screw into both the plate and the bone to stabilize their relative positions. All of the holes in the claims-at-issue are at least partially threaded so that physicians can optionally use locking screws or nonlocking bone screws.

In 2009, Smith & Nephew, Inc. ("Smith & Nephew") requested reexamination of the '744 patent. On reexamination, the PTO rejected all fifty-five claims as obvious based on numerous prior art references, including a 1997 article by N.P. Haas ("the Haas article") and Synthes devices from the 1990s ("the Synthes devices").

The Haas article disclosed a plate with only conically tapered, threaded holes in the shaft and head portions of the plate. The Synthes devices included (1) a plate with unthreaded holes for fractures in the femur; (2) a Distal Radius Plate ("DRP") for wrist fractures with all anchor holes partially threaded and designed for use with either locking or nonlocking screws; and (3) a Locking Reconstruction Plate ("LRP") for jaw fractures with anchor holes having threaded lower portions and unthreaded, conically flared upper portions that allowed for countersunk screws.

According to the examiner, combining the Haas article with any of the references cited taught the claimed invention. The examiner also adopted Smith & Nephew's argument that there was a motivation to combine the references because having all screw holes threaded would provide the option of using either locking screws for stability or compression screws to quicken healing. Synthes then appealed to the Board.

On appeal, the Board reversed the rejections of twenty-four claims, concluding that it would not have been obvious to modify the prior art to have only threaded holes in the plate's head portions. According to the Board, the prior art did not teach the use of only conical, partially threaded holes in a bone plate because those holes could not be used with nonlocking screws to provide compression. And although the '744 patent stated that the partially threaded holes of the Synthes devices could be used with nonlocking screws to obtain compression, that admission was not fatal to Synthes's case because the Synthes devices' plate holes were not fully conical from the top surface to the bottom surface of the plate. Regarding the Haas article, the Board found that the holes were both threaded and fully conical, but that one of ordinary skill would not have used a nonlocking screw with the disclosure in the Haas article for two reasons. First, there was no evidence that conical, partially threaded holes could be used with nonlocking screws. Second, using a nonlocking screw with that disclosure would result in an inadequately countersunk screw. Following the Board's reversal, Smith & Nephew appealed.

On appeal, the Federal Circuit reversed the Board's decision on the twenty-four claims, finding several flaws with the Board's analysis. First, the Court held that the Board erred in distinguishing between the '744 patent and the prior art on the ground that it would not have been obvious to use a nonlocking screw in a threaded hole to provide compression. Here, the Court held that the claims-at-issue did not require that the screws provide compression.

"Expert opinions that are contrary to admissions in the specification do not create a factual issue." Slip op. at 15 n.6 (citing *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1361-62 (Fed. Cir. 2007)).

Second, the Court held that the Board erred in its conclusion regarding countersunk screw features. Nothing in the Haas article, the Court determined, limited the size of the described features or indicated that the geometries could not be made larger to adequately countersink screws. And even if countersinking were not an option, a person of ordinary skill could simply choose an appropriately shaped screw that would sit within the holes without protruding.

Third, the Court found improper the Board's finding that partially threaded holes in the prior art that were only partly conical could not accept nonlocking screws. By the '744 patent's own admission, partially threaded holes, regardless of their shape, were compatible with nonlocking screws because a person of skill could change a hole's geometry to fit any nonlocking screw and achieve compression.

Fourth, the Court held that the Board erred in not considering the DRP and LRP devices on the ground that the examiner had not relied on them as a basis for the rejections. On this point, the Federal Circuit determined that the examiner incorporated by reference Smith & Nephew's arguments, including its discussion of the DRP and LRP devices. The Court also found unpersuasive Synthes's attempt to distinguish the prior art by arguing that the references were not used with weight-bearing bones and therefore used holes with only minimal threading.

Although recognizing that the substantial evidence standard of review required it to defer to the Board's findings, the Court nonetheless determined that the facts of the case were largely undisputed, while the decision was the result of analytical errors. To the extent that Synthes intended to create a factual dispute through an expert declaration that it submitted, the Court found the declaration contrary to the '744 patent's specification and held that "[e]xpert opinions that are contrary to admissions in the specification do not create a factual isssue." Slip op. at 15 n.6 (citing *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1361-62 (Fed. Cir. 2007)).

The Court also addressed whether it would have been obvious to combine the prior art. On this issue, the Court held that the evidence did not indicate that the available choices in the prior art would produce a surprising result or involve anything more than a choice among designs already known. According to

the Court, the claims-at-issue entailed "an improvement that is no 'more than the predictable use of prior art elements according to their established functions.'" *Id*. at 17 (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)).

Finally, the Court addressed Synthes's argument that achieving compression with nonlocking screws in conically tapered, partially threaded holes was previously unknown and would have been inoperable. According to Synthes, this objective became possible only through the use of specialized screws. In rejecting the argument, the Court held that "[t]he problem with Synthes's argument is that it is contending that a standard non-locking screw would be inoperative to obtain compression in a threaded hole, while at the same time claiming that it managed to achieve exactly that objective, all through the *deus ex machina* of a 'specialized screw'" that was an unclaimed and undisclosed feature in the '744 patent. *Id.*

Accordingly, the Court reversed the Board's decision, holding that the examiner correctly ruled that the disputed claims would have been obvious.

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Additional Detail Provided in Board's Explanation Does Not Constitute New Ground of Rejection

Hillary C. Matheson

Judges: Prost, Reyna, Wallach (author)

[Appealed from Board]

In *In re Adler*, No. 12-1610 (Fed. Cir. July 18, 2013), the Federal Circuit affirmed the Board's decision upholding the examiner's final rejection of the pending claims of U.S. Patent Application No. 10/097,096 ("the '096 application") by Doron Adler, Ofra Zinaty, Daphna Levy, and Arkady Glukhovsky (collectively "Adler") as obvious over several prior art references and found that the Board did not rely on new grounds for rejection.

The '096 application is directed in part to a system for detecting blood within a body lumen, such as the esophagus. The system includes a swallowable capsule with an in vivo imager for obtaining images from within the body lumen. The images obtained can then be compared to two reference values: one for healthy tissue and one for blood.

The examiner rejected the claims-at-issue as being obvious over several prior art references, including "Meron" in view of "Hirata." The examiner found that Meron disclosed a capsule that moves through the gastrointestinal tract to generate a map of the tract. The examiner also found that Hirata taught a study of factors of esophageal variceal rupture using image processing with a video endoscope. The examiner concluded it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate a processor for the colorimetric analysis of video endoscopic data, as taught by Hirata, in order to determine the presence of blood, as stated by Meron. The examiner reasoned that it would have been obvious because Meron states it is capable of determining the presence of blood but fails to provide the specifics of how, while Hirata provides a method and a processor capable of performing these feats. The examiner's rejections were appealed, and the Board affirmed.

"While the Board's explanation may go into more detail than the examiner's, that does not amount to a new ground of rejection." Slip op. at 10.

On appeal, the Federal Circuit noted that the primary issue was whether the Board properly found that it would have been obvious, in light of the prior art, to compare reference values for healthy tissue and blood to determine whether images of the gastrointestinal tract showed a change in the level of red color content where that change correlates to the presence of blood, as articulated in the claims-at-issue. The Court explained that, contrary to Adler's argument, the Board appreciated that the claims require two comparisons of the values for the received images: first to a value for healthy tissue and second to a

value for blood. The Court held that substantial evidence supported the Board's finding that Hirata discloses analyzing color tone by comparing a defined varices region with a defined normal esophageal region. The Court, discussing the Board's rationale, further explained that one of ordinary skill in the art would equate the color red with current bleeding and would be motivated to build on Meron's teachings concerning images received from a swallowable device that could be compared to the reference values disclosed in Hirata. The Court stated that the claim was a predictable variation of the combination of Hirata and Meron.

In addressing Adler's argument that the Board relied on a new ground for rejection of the claims-at-issue and instead should have reopened prosecution, the Court determined that Adler mischaracterized the examiner's grounds for rejection, and neither pointed to specific facts found by the Board but not by the examiner, nor illustrated how any such facts formed the basis of the Board's rejection. The Court noted that, in rejecting the application, the examiner relied on Hirata's disclosure not just for its use of the color sign classification, but for the red color tone as well. Contrary to Adler's contention that the examiner made no mention of colorimetric analysis, the Court found the examiner expressly referred to that feature of Hirata by name. Finally, the ultimate criterion of whether a rejection is considered new in a decision by the Board is whether applicants have had fair opportunity to react to the thrust of the rejection. The Court indicated that Adler had the opportunity to respond—and, in fact, did respond—to the thrust of the examiner's basis for rejecting the claims.

Accordingly, the Court concluded that the Board did not err in rejecting the pending claims as obvious over Meron in view of Hirata and did not rely on new grounds for rejection.

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Written Description Not Satisfied for Narrow Claims Where Disclosure Provides Only Generalized Guidance That May or May Not Lead to Useful Result

Lillian M. Robinson

Judges: Rader (dissenting), Schall (author), Bryson

[Appealed from W.D. Wis., Senior Judge Crabb]

In *Novozymes A/S v. DuPont Nutrition Biosciences APS*, No. 12-1433 (Fed. Cir. July 22, 2013), the Federal Circuit affirmed the district court's JMOL that the claims of U.S. Patent No. 7,713,723 ("the '723 patent") are invalid for failing to satisfy the written description requirement under 35 U.S.C. § 112.

Plaintiffs Novozymes A/S and Novozymes North America, Inc. (collectively "Novozymes") and Defendants DuPont Nutrition Biosciences APS, Genencor International Wisconsin, Inc., Danisco US Inc., and Danisco USA Inc. (collectively "DuPont") compete in the market of commercial enzyme preparation. The '723 patent contains claims to particular modified alpha-amylase enzymes that exhibit improved function and stability under certain conditions, and claims priority from and has a nearly identical written description as a provisional application filed in 2000 ("the 2000 application"). Novozymes sued DuPont for infringement of the '723 patent, and DuPont defended, inter alia, on the grounds of invalidity under the written description and enablement requirements. A jury found that the '723 patent was not invalid and awarded infringement damages to Novozymes. The district court, however, granted DuPont's JMOL motion that the claims of the '723 patent are invalid for inadequate written description in the 2000 application. Novozymes appealed.

"[O]ne searches the 2000 application in vain for the disclosure of even a single species that falls within the claims or for any 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." Slip op. at 24.

On appeal, the Federal Circuit held that no reasonable jury could find that the claims of the '723 patent meet the written description requirement, and that the district court correctly entered JMOL invalidating the claims. The Court reasoned that "[i]n contrast to the claims—which narrowly recite specific alpha-amylase variants that result from mutating a particular parent enzyme at a single amino acid position to yield distinctive functional properties—the supporting disclosure of the 2000 application provides only generalized guidance listing several variables that might, in some combination, lead to a useful result." Slip op. at 18. The Court held that "[t]aking the claims as a whole rather than as the sum of their individual limitations, nothing in the 2000 application indicates that Novozymes then possessed what it now claims." *Id.* The Court further concluded that the testimony of Novozymes's experts did not

overcome the fundamental deficiencies of the 2000 application's written description.

The Court noted, as argued by Novozymes, that each of the individual claim limitations could be found in the specification and thus had "formal textual support" in the disclosure of the 2000 application, but that the combination of variables that constituted the later claimed subject matter was nowhere described. As stated by the Court, "one searches the 2000 application in vain for the disclosure of even a single species that falls within the claims or for any 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." *Id.* at 24. The Court noted that the bulk of the 2000 application focused on a different parent enzyme than that of the '723 patent, that the amino acid position targeted in the '723 patent was only one of thirty-three positions that could be altered, that the 2000 application only specifically described one substitution at that position, and that the parties agreed that such a substitution would fall outside the claims of the '723 patent because it did not confer increased thermostability.

The Court rejected Novozymes's argument that one of ordinary skill in the art directed to position 239 would have known how to test every possible variant at that position and thus would have found the claimed variants as a matter of course. The Court stated that the question before them was not whether one of ordinary skill in the art would have been enabled to take the final step of testing variants at the 239 position, but whether the 2000 application actually guided one skilled in the art to make a variant at 239 with the particular properties claimed some ten years later out of a slew of competing possibilities. As mentioned above, the Court found that there was nothing in the 2000 application that would have led one skilled in the art to the variants later claimed, and specifically held that one could not use knowledge of the later claimed subject matter as a guide to "pluck" from the specification the necessary claim limitations. Accordingly, the Court found that the 2000 application did not show possession of the claimed invention, stating that the application was "[a]t best, . . . a roadmap for producing candidate alpha-amylase variants and then determining which might exhibit enhanced thermostability." *Id.* at 27. Because "[a] patent . . . 'is not a reward for the search, but compensation for its successful conclusion,' . . . the written description requirement forbids a patentee from 'leaving it to the . . . industry to complete an unfinished invention.'" *Id.* (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc)).

The Court found Novozymes's remaining arguments unpersuasive and concluded that the claims of the '723 patent are invalid for failure to satisfy the written description requirement. The Court thus affirmed the district court's JMOL on that basis.

Chief Judge Rader dissented, stating that "[the Court's] written description rules urge reversing the district court's post-verdict grant of judgment." Rader Dissent at 2. In Judge Rader's view, substantial evidence supported the jury's determination that the claims were not invalid for failing to satisfy the written description requirement. In particular, Judge Rader noted that it was sufficient that the specification disclosed "well-known" tests for "determining activity and thermostability at the claimed conditions." *Id.* at 3.

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Court Finds Inadequate Written Description for Certain Claims Requiring the Exclusion of a Specific Species

Victoria S. Lee

Judges: Rader (concurring), Clevenger (author), Prost

[Appealed from Board]

In *In re Bimeda Research & Development Ltd.*, No. 12-1420 (Fed. Cir. July 25, 2013), the Federal Circuit affirmed the Board's rejection of certain claims introduced during ex parte reexamination of U.S. Patent No. 6,506,400 ("the '400 patent") for not meeting the written description requirement.

The '400 patent is owned by Bimeda Research & Development Limited ("Bimeda") and concerns methods for preventing the onset of bovine mastitis, the inflammation of udder tissue in cows. Specifically, the '400 patent claims "prophylactic method[s] of controlling infection in a mammary gland by a mastitis-causing organism, comprising sealing a teat canal of a mammary gland with a seal formulation so as to provide a physical barrier in the teat canal." Slip op. at 3 (citation omitted). During ex parte reexamination of the '400 patent, Bimeda added new claims 18-39. The examiner allowed independent claims 18 and 26, which respectively recited that the seal formulation was free of antiinfective agents and had no bacterial action, and their dependent claims.

The examiner, however, rejected claims 32-39, which recited that the seal formulation was free of the antiinfective agent acriflavine. The examiner based the rejections on 35 U.S.C. § 112, ¶ 1, and the Board affirmed. The Board concluded that where a patent disclosure describes the exclusion of a broad genus, claims to embodiments that exclude particular species are only supported if the disclosure offers some guidance for excluding that particular species. Bimeda appealed the Board's decision to the Federal Circuit.

On appeal, Bimeda argued that the disclosure broadly claims a teat seal formulation utilizing a physical barrier but does not expressly exclude any particular antiinfective agents. The Court stated that Bimeda interprets this "as tacit indifference to the presence or absence of specific antiinfectives," and therefore supported a claim that excluded one particular antiinfective (acriflavine) while permitting the use of others (antibiotics). *Id.* at 6. The Federal Circuit instead found that substantial evidence supported the Board's contrary interpretation. The Court concluded that the disclosure was generally inconsistent with a formulation that excluded acriflavine but could include antibiotics. The Court stated that "the summary of the invention describes the invention's 'non-antibiotic approach' to preventing mastitis," and that "[t]he remainder of the disclosure similarly distinguishes the invention due to its ability to prevent mastitis without using antibiotics." *Id.* at 6-7. The Court thus concluded that substantial evidence supported the Board's finding that the '400 patent's disclosure did not convey possession of the literal scope of claim 32, and affirmed the Board's decision with regard to claims 32-39.

Chief Judge Rader wrote a separate concurring opinion to "highlight" the Board's "problematic alternative rationale." Rader Concurrence at 1. Chief Judge Rader opined that "[t]he repeated references to 'possession,' i.e. the traditional nomenclature for discussing written description, illustrate the weakness in using this framework for all written description cases." *Id.* According to Chief Judge Rader, "the Board refused to wrestle with the fact that the claim at issue (and the patent as a whole) focuses on negative claiming," and thus "places the patentee into a Catch-22: to satisfy written description, the patentee must show possession of something it specifically claims it does not possess." *Id.* at 2.

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For SJ, a Court Must Accept the Nonmoving Party's Expert's Factual Assertions as True

Abhay A. Watwe

Judges: Dyk, Mayer, Moore (author)

[Appealed from S.D. Iowa, Senior Judge Wolle]

In *Charles Machine Works, Inc. v. Vermeer Manufacturing Co.*, No. 12-1578 (Fed. Cir. July 26, 2013), the Federal Circuit vacated-in-part and remanded the district court's grant of SJ of noninfringement of Vermeer Manufacturing Company's ("Vermeer") commercial products and noncommercial prototypes, holding that The Charles Machine Works, Inc. ("CMW") did not have sufficient notice that the prototypes were within the scope of the SJ. Additionally, with regard to Vermeer's accused commercial products, the Court affirmed the district court's SJ of no literal infringement but reversed the district court's SJ of noninfringement under the DOE and remanded.

This case concerns U.S. Patent No. 5,490,569 ("the '569 patent"), which generally relates to a two-pipe drill for boring underground holes in the horizontal direction. An inner pipe rotates the drill bit, while an outer pipe, which includes a body and casing, is used for steering. A deflection shoe included on one side of the casing creates an asymmetry about the casing's centerline axis. When the casing does not rotate, the deflection shoe causes the drill to deflect away from a straight path. When the casing rotates, however, the drill follows a straight horizontal path.

CMW alleged infringement by two types of Vermeer drills: noncommercial prototypes and commercial products, both of which include a structure called a "bent sub." CMW contended that the bent sub met the "deflection shoe" and "mounted on" limitations of the asserted claims. The district court granted Vermeer's SJ motion for noninfringement as to all accused products. CMW appealed the district court's decision.

"The term 'accused products' could in a colloquial sense arguably include all of the accused products. Here, however, the proposed rulings were expressly limited to 'COMMERCIAL' products. The internal use of 'accused products' did not expand the motion beyond its own express limits." Slip op. at 5.

The Federal Circuit vacated and remanded the district court's grant of SJ of noninfringement by Vermeer's noncommercial prototypes. In doing so, the Court focused on Vermeer's SJ motion and the statements made by both parties at the SJ motion hearing. The Court noted that Vermeer titled its own moving papers as a "MOTION FOR SUMMARY JUDGMENT THAT VERMEER'S COMMERCIAL PRODUCTS DO NOT INFRINGE" and that Vermeer's SJ motion made no substantive arguments

regarding the prototypes. Slip op. at 4. The Court also noted that Vermeer's proposed rulings were expressly limited to "COMMERCIAL" products. *Id.* In addition, the Court observed that at the SJ hearing, Vermeer stated that its motion was limited to the commercial products and that an SJ on its motion would not end CMW's claims on three prototype units, which were never sold. In contrast, the Court noted that CMW's statements at the hearing did not indicate that the prototypes were part of SJ. The Court, therefore, concluded that CMW had insufficient notice that the SJ decision would include the accused prototypes, vacated the grant of SJ of noninfringement by the prototypes, and remanded.

With regard to literal infringement by Vermeer's commercial products, the Court noted that the parties had limited their arguments about literal infringement to the correctness of the district court's claim construction. Because the Court found no error in that claim construction, the Court affirmed the district court's grant of SJ of no literal infringement by the accused commercial products.

The Court, however, reversed the district court's grant of SJ of noninfringement of the accused commercial products under the DOE. In doing so, the Court focused on the CMW expert's function-way-result analysis and concluded that the expert's declaration had established genuine disputes about equivalence. Specifically, the Court noted the expert's opinion that the bent sub on the accused products and the deflection shoe in the claims of the '569 patent performed the same function—that of deflecting the drill from a linear path. The Court also noted the expert's opinion that both structures performed the function in substantially the same way because both had a portion disposed outside the cutting circle of the drill bit, which reacted with the side of the bore hole and caused the drill bit to deflect from a linear path. In addition, the Court noted the expert's opinion that both structures achieved the same result of deflecting the drill bit in a direction opposite the deflection shoe. Noting that for purposes of SJ, the Court must accept CMW's expert's factual assertions as true, the Court held that the expert's assertions raised genuine factual disputes material to the function-way-result inquiries. The Court, therefore, concluded that a reasonable jury could have found equivalence, and held that the district court erred by making a contrary legal determination.

Vermeer had also argued that a finding of equivalence would read the "deflection shoe" and "mounted on" limitations out of the claims and is thus barred by the doctrine of claim vitiation. The Court, however, concluded that the doctrine of claim vitiation did not bar CMW's application of the DOE.

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Contradictory Statements in Prosecution May Lead to Invalidity by Indefiniteness

Jeffrey D. Smyth

Judges: Rader, Moore (author), Benson (sitting by designation)

[Appealed from S.D.N.Y., Judge Jones]

In *Teva Pharmaceutials USA, Inc. v. Sandoz, Inc.*, Nos. 12-1567, -1568, -1569, -1570 (Fed. Cir. July 26, 2013), the Federal Circuit affirmed the district court's judgments of infringement and no invalidity with respect to one set of claims, reversed its judgment of no invalidity with respect to another set of claims, and remanded for further proceedings.

Teva Pharmaceuticals USA, Inc. ("Teva") markets Copaxone®, a drug used for treating multiple sclerosis. Sandoz, Inc. ("Sandoz") and Mylan Pharmaceuticals Inc. ("Mylan") (collectively "Defendants") submitted ANDAs to the FDA seeking approval to market generic versions of Copaxone®. Teva sued the Defendants for infringement of the patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") entry for Copaxone®.

The patents-in-suit include claims reciting a product called copolymer-1, which consists of four different amino acids combined in a specific ratio. Samples of copolymer-1 consist of a mixture of molecules that have varying molecular weights. Two different methods exist for measuring the distribution of molecular weights in a given sample. The first method uses statistical measures, including the peak average molecular weight (M_p), number average molecular weight (M_n), and weight average molecular weight (M_w). In a typical sample, these three measures have different values. The second method measures a sample by the number of molecular weights falling within an arbitrarily set range. For example, a sample may be described as having 99% of its mole fraction within the molecular weight range of 1 kilodalton (kDa) and 100 kDa. Teva asserted claims using both types of measurement against Sandoz and Mylan. Claims using the first method of measurement are termed "Group I" claims and those using the second method are categorized as "Group II." Both methods of claims contain the term "molecular weight."

In its claim construction order, the district court did not distinguish between the different contexts (Group I or Group II) when construing the term "molecular weight." It construed "molecular weight" to mean M_p and rejected arguments that the claims were indefinite. After a bench trial, the district court found the asserted claims valid and infringed by the accused Sandoz and Mylan products. Sandoz and Mylan appealed.

On appeal, the Federal Circuit first addressed this issue of definiteness. The Court found the term "molecular weight" ambiguous in the context of the Group I claims, rendering the Group I claims indefinite. The plain language of the Group I claims does not indicate which molecular weight measure is intended: M_p, M_n, or M_w. The Court noted that in overcoming one rejection during prosecution, Teva stated that molecular weight meant M_p, but in overcoming a separate rejection in a related application,

Teva argued that molecular weight meant M_w. Rejecting Teva's reliance on the prosecution history to resolve the ambiguity, the Court determined that the two definitions could not be reconciled and held that the contradiction rendered the ambiguity insoluble.

"It is undisputed that Group I claims contain an ambiguity because their plain language does not indicate which average molecular weight measure is intended. Teva's attempt to resolve this ambiguity hinges in part on the prosecution history. But two of its prosecution statements directly contradict each other and render the ambiguity insoluble." Slip op. at 8.

The Court's reasoning did not apply to the Group II claims. The Court explained that, in contrast to the Group I claims, which recite average molecular weight values, the Group II claims recite the percentage of copolymer-1 falling within a set molecular weight range. Thus, the numbers setting the boundaries in those claims set precise points on the "molecular weight" scale. Because the claims refer to exact values rather than statistical measures, the scope of the Group II claims is readily ascertainable and not indefinite.

The Court continued its analysis of the Group II claims, considering whether they were sufficiently enabled. The district court found that the claims were sufficiently enabled because a person of skill in the art would be able to measure the claimed molecular weight using known calibration methods. The Federal Circuit agreed, finding no clear error on the part of the district court. The Court reasoned that Teva's expert testified at length that it would have been routine for a skilled artisan to measure the molecular weight of copolymer-1 and that the district court did not err in finding the testimony more convincing than the testimony offered by opposing experts. Accordingly, the Court affirmed the district court's finding of no invalidity for lack of enablement.

The Federal Circuit also affirmed the district court's finding in favor of Teva on the issue of obviousness. The district court found that the asserted claims would not have been obvious in view of copolymer-1 compounds with a molecular weight higher than 10 kDa, as disclosed in the prior art. The district court found that prior art references explicitly taught away from the claimed lower molecular weight copolymer-1 and that various secondary considerations indicated nonobviousness. The Federal Circuit agreed, holding that the district court did not clearly err when it found that the prior art expressed a preference for higher molecular weight copolymer-1, thereby teaching away from the claimed invention, or when finding that secondary considerations supported a finding of nonobviousness. Accordingly, the Court affirmed the district court's finding of no invalidity for obviousness.

Finally, the Federal Circuit addressed infringement. The district court construed "copolymer-1" to mean a mixture of polypeptides composed of alanine, glutamic acid, lysine, and tyrosine in a molar ratio of approximately 6:2:5:1, a construction that was not in dispute. In considering infringement, the district court determined that an accused product meets the claim limitations as long as its amino acid composition does not vary from the "ideal" percentages by an aggregate of more than 12%. Finding that the accused products from both Sandoz and Mylan vary by less than 5%, the district court ruled that both products infringed literally. The Court held that the district court did not err in its methodology, noting that the conclusion was supported by prior art examples of copolymer-1, which showed that even when one of the amino acids differs from its ideal percentage by more than 5%, the material is still considered "copolymer-1."

The Court also rejected the argument that Teva surrendered claims to copolymer-1 with a molecular weight greater than 10 kDa, as measured by M_w. The Court reasoned that the phrase "molecular weight of 10 kilodaltons" does not expressly refer to any specific molecular weight measurement. This finding, the basis for finding the Group I claims indefinite, also resulted in a finding that the connection between Teva's statement and the prior art was too attenuated to limit the scope of the claims to copolymer-1 with

M_w less than 10 kDa. Thus, the Court affirmed the infringement finding.

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Patentee's Election of Species in Response to Ambiguous Restriction Requirement During Prosecution Is Not a Basis for Narrowly Construing a Broadly Drafted Claim

K. Kevin Mun

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

[Appealed from N.D. Cal., Magistrate Judge Zimmerman]

In *Plantronics, Inc. v. Aliph, Inc.*, No. 12-1355 (Fed. Cir. July 31, 2013), the Federal Circuit reversed-in-part and vacated-in-part the district court's partial SJ of noninfringement and invalidity for obviousness, and remanded for further proceedings.

Plantronics, Inc. ("Plantronics") filed suit against Aliph, Inc. and Aliphcom, Inc. (collectively "Aliph"), alleging infringement of U.S. Patent No. 5,712,453 ("the '453 patent"). The '453 patent is directed to a concha-style stabilizer for headsets transmitting sounds to the ear of a user. Independent claim 1 recites "[a]n apparatus for stabilizing a headset . . . , the apparatus comprising: . . . a resilient and flexible *stabilizer support member* . . . ," and independent claim 10 recites "[a] headset comprising . . . a *concha stabilizer* . . . ." Slip op. at 5.

The district court construed the terms "stabilizer support member" in claim 1 and "concha stabilizer" in claim 10 and, based on its constructions, granted SJ of noninfringement. The district court also granted SJ of invalidity for obviousness of the asserted claims. Plantronics appealed.

"The election of an invention in response to an ambiguous restriction requirement . . . cannot be said to provide any guidance forming a basis for narrowing a broadly drafted claim." Slip op. at 11 (citing *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003)).

On appeal, the Federal Circuit held that the district court erred in construing the terms "stabilizer support member" and "concha stabilizer." The Court reasoned that by construing "stabilizer support member" and "concha stabilizer" as "elongated" structures, further defined by the district court as "longer than it is wide," the district court introduced a narrowing structural limitation to the claims. *Id.* at 8 (citation omitted). In the Court's view, based on the claim language, the specification, and the prosecution history, "[t]hose terms require a meaning that is not as limiting as the district court imposed." *Id.* With regard to the prosecution history, the Court stated that Plantronics's "election of an invention in response to an ambiguous restriction requirement . . . cannot be said to provide any guidance forming a basis for narrowing a broadly drafted claim." *Id.* at 11 (citing *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003)). In particular, the Court rejected Aliph's argument that an election during prosecution related to the form of the stabilizer support: "We cannot discern from the

correspondence between the PTO and Plantronics whether the 'stabilizer support member' and the 'concha stabilizer' were interpreted by any party to contain particular structural limitations." *Id.* at 13-14. The Court concluded that the '453 patent supports broader constructions, and construed the terms "stabilizer support member" and "concha stabilizer" without requiring an "elongated" structure that is "longer than it is wide." *Id.* at 14. As a result of the new construction, the Court vacated the district court's SJ of infringement and remanded for further proceedings.

Regarding invalidity, the Federal Circuit held that the district court erred in granting SJ of obviousness. The Court noted that "[t]he gravamen of the parties' dispute here involved whether a skilled artisan would have been motivated to combine certain prior art references, an issue that focuses heavily on the first and third *Graham* factors." *Id.* at 16. The Court noted that the district court did not cite any expert testimony indicating that there was a motivation to combine the prior art references, instead determining that common sense provided the motivation. The Court concluded that although the obviousness analysis is somewhat flexible, the record lacked the necessary reasoning by the district court to support its determination that common sense would provide the motivation to combine.

Further, the Court held that the district court erred by reaching its obviousness conclusion before considering Plantronics's objective evidence of nonobviousness, which included copying and commercial success. The Court stated that "[t]he significance of this fourth *Graham* factor cannot be overlooked or by relegated to 'secondary status,'" noting that "[t]he objective considerations, when considered with the balance of the obviousness evidence in the record, guard as a check against hindsight bias." *Id.* at 19 (citations omitted). The Court concluded that the district court's opinion lacked "sufficient findings and reasoning to permit meaningful appellate scrutiny." *Id.* at 21 (quoting *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 707 (Fed. Cir. 2012)).

The Court further stated that it could not discern whether the district court, in this SJ context, drew all justifiable inferences in favor of Plantronics and found no disputed issues of material fact to support its holding with respect to obviousness. The Court concluded that the objective evidence of nonobviousness raises genuine issues of material fact, and thus reversed the district court's grant of SJ of invalidity.

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Looking Ahead

On August 7, 2013, in *Apple Inc. v. International Trade Commission*, No. 12-1338 (Fed. Cir. Aug. 7, 2013), the Federal Circuit considered Apple Inc.'s ("Apple") challenge of the ITC's determinations of obviousness, anticipation, and noninfringement, ultimately affirming-in-part, reversing-in-part, and vacating-in-part the ITC's decision. In particular, the Court noted that they were troubled by the ITC's obviousness analysis, and indicated that all four *Graham* factors, including objective evidence of secondary considerations, must be considered in the obviousness determination. "The ITC, however, never even mentioned, much less weighed as part of the obviousness analysis, the secondary consideration evidence Apple presented." Slip op. at 15. Citing numerous examples of industry praise and commercial success regarding the iPhone, the Court found that the ITC's failure to address these secondary considerations was in error, and the Court vacated the ITC's determination that certain claims of Apple's patent would have been obvious.

Judge Reyna concurred-in-part and dissented-in-part, providing insight into his views regarding the purpose and function of objective indicia of nonobviousness. Specifically, Judge Reyna expressed his view that "objective evidence of nonobviousness is objective indicia of innovation." Reyna Concurrence-in-Part and Dissent-in-Part at 14. Judge Reyna further opined that "[w]e must not lose sight that a patent, presumed valid, commemorates an inventor's achievement that entitles her to full and equal consideration of all evidence before a conclusion on the issue of obviousness is reached. Our patent laws are designed to foster optimal incentives for innovation, yet too often the genius of an invention is dismissed by combination of known elements viewed through glasses of hindsight." *Id.* Judge Reyna noted, however, that the ITC succumbed to the bias of hindsight as the record included significant objective evidence that Apple's patent was innovative and therefore nonobvious.

Read the full summary in the next edition of *Last Month at the Federal Circuit*.

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Spotlight Info

In *Plantronics, Inc. v. Aliph, Inc.*, No. 12-1355 (Fed. Cir. July 31, 2013), the Federal Circuit reversed-in-part and vacated-in-part the district court's grant-in-part of SJ of noninfringement and invalidity for obviousness, and remanded for further proceedings. The patent-in-suit is directed to a concha-style headset for transmitting received sounds to the wearer's ear. In granting SJ of obviousness, the Court found that the district court erred, noting that it did not cite any expert testimony indicating there was a motivation to combine the prior art references, instead determining that common sense provided the motivation. The Court concluded that although the obviousness analysis is somewhat flexible, the record lacked the necessary reasoning by the district court to support its determination that common sense would provide the motivation to combine. See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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