Last month at | The Federal Circuit

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Month at a Glance

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This publication brings you a synopsis of patent cases decided last month by the United States Court of Appeals for the Federal Circuit based on slip opinions received from the court. You can review and download the full text of each opinion by visiting our website at *www.finnegan.com*

Rewriting Dependent Claims in Independent Form Triggers Estoppel

Lara C. Kelley

[Judges: Mayer (author), Clevenger, and Bryson]

In *Ranbaxy Pharmaceuticals, Inc. v. Apotex, Inc.*, No. 02-1429 (Fed. Cir. Nov. 26, 2003), the Federal Circuit affirmed a district court's denial of a preliminary injunction against Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy").

Apotex, Inc. ("Apotex") and Ranbaxy are generic drug manufacturers, who both seek to market amorphous cefuroxime axetil, a broad-spectrum antibiotic. Apotex is the owner of U.S. Patent No. 5,847,118 ("the '118 patent"), which is directed to a process for preparing amorphous cefuroxime axetil. Ranbaxy sought a DJ that it does not infringe the claims of the '118 patent. Apotex counterclaimed and moved for a preliminary injunction, arguing that Ranbaxy was infringing the claims of the '118 patent under the DOE. Apotex conceded that there was no literal infringement. Thus, the sole issue before the district court when making its decision on the preliminary injunction motion was Apotex's likelihood of success on its DOE theory. The district court concluded that prosecution history estoppel precluded Apotex's reliance on the DOE.

Apotex's original independent claim was for a process of making amorphous cefuroxime axetil using "a highly polar organic solvent," which dependent claims further limited to sulfoxide, formic acid, or an amide. During prosecution, the independent claim was rejected under 35 U.S.C. § 112, ¶ 2, the Examiner asserting that the term "highly polar organic solvent" was indefinite. Additionally, the independent claim was rejected under 35 U.S.C. § 103(a) as obvious over a prior art process of making the drug using acetone, which the Examiner assumed was a highly polar organic solvent. The dependent claims specifying particular solvents were objected to and indicated as being allowable if rewritten in independent form. In response, Apotex canceled the pending claims and replaced them with all new claims; the only independent claim presented ultimately became claim 1 of the '118 patent and was limited to the particular solvents recited in the previously objected-to dependent claims.

Ranbaxy's alleged infringing process uses acetic acid rather than the specifically recited solvents, and so Apotex moved for a preliminary injunction alleging infringement under the DOE. The district court found that prosecution history estoppel precluded Apotex's reliance on the DOE because: (1) Apotex had submitted a narrowing amendment for reasons related to patentability, and (2) Apotex had surrendered solvents of the same polarity as acetone, namely, acetic acid.

On appeal, the Federal Circuit addressed the issue of whether rewriting a dependent claim in independent form triggers prosecution history estoppel by first distinguishing its *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354 (Fed. Cir. 2001), decision. The Court observed that *Bose* had held that rewriting a claim to explicitly recite a previously inherent feature did not trigger estoppel, but that it had not addressed the issue of rewriting a dependent claim in independent form. The Federal Circuit stated that the correct focus for determining whether a narrowing amendment has been made is on whether subject matter that was originally claimed was surrendered for reasons related to patentability. The Court found that rewriting the dependent claims that recited specific highly polar organic solvents in independent form further defined and circumscribed the existing limitation of "highly polar organic solvent" for the purpose of putting the claims in condition for allowance.

In addressing whether Apotex could overcome the presumption of surrender, the Federal Circuit rejected Apotex's argument that it could not have foreseen that reciting particular solvents would constitute a surrender of an obvious structural equivalent of those solvents, particularly in light of Apotex's arguments that acetic acid was a known equivalent. However, the Federal Circuit observed that, before the district court, there was a dispute among the experts on the issue of the proper method of determining polarity. As such, the Federal Circuit noted that Apotex may be able to present sufficient evidence to rebut the presumption of surrender, and if so, the trier of fact must determine the proper method of determining polarity and whether acetic acid and acetone have the same polarity.

35 U.S.C. § 121's Shield Applies to Formal PTO Restriction Requirements

Michael J. Leib

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

In *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, No. 02-1439 (Fed. Cir. Nov. 21, 2003), the Federal Circuit affirmed a district court's judgment invalidating the claims of several patents for nonstatutory double patenting.

GlaxoSmithKline, PLC et al. ("GSK") own the eight patents-in-suit, which all originate from the same parent application, U.S. Patent Application No. 05/569,007 ("the '007 application"). The eight patents-in-suit can be divided into two groups: those patents that issued in 2000-2001 ("the 2000/01 patents"), and those patents that issued in 1985 ("the 1985 patents"), which include U.S. Patent Nos. 4,525,352 ("the '352 patent"); 4,529,720 ("the '720 patent"); and 4,560,552 ("the '552 patent").

The patents-in-suit relate to the antibiotic clavulanic acid and its salts. Clavulanic acid retains an ability to protect a variety of antibiotics against a number of enzymes produced by bacteria, such as ß-lactamase, that render antibiotics useless. Specifically, the patents-in-suit claim clavulanic acid in combination with antibiotics like amoxicillin or penicillin, and methods of using clavulanic acid and its salts to inhibit ß-lactamase.

Geneva Pharmaceuticals, Inc. filed DJ suits against GSK challenging the validity of the 2000/01 and 1985 patents. Upon motions for SJ, the district court held the 2000/01 patents invalid for nonstatutory double patenting over the '720 patent. The district court ruled that 35 U.S.C. § 121 did not shield the 2000/01 patents against invalidity over the '720 patent. Subsequently, after a bench trial, the district court invalidated the 1985 patents on nonstatutory double-patenting grounds over two expired GSK patents, the Crowley patent and the Fleming patent.

On appeal, the Federal Circuit affirmed the district court and held that § 121 did not shield the 2000/01 patents from double-patenting invalidity over the '720 patent for two reasons. First, the Court determined that the 2000/01 patents and the '720 patents did not trace their lineage back to a common parent, a requirement to obtain § 121 protection, because the method of use claims, which appear in the '720 patent, were never pending in the original '007 application. To protect a patent from a double-patenting rejection, § 121 requires that the claims later sought to be shielded must appear in a parent application before a restriction requirement is issued. According to the Court, section 121 does not shield claims merely because the parent application provides some support for claims that are first entered in subsequent related applications. In this case, the '720 patent's claims never appeared in the original '007 application. Because of this, the '720 patent could not have been a formal divisional of the '007 application so that § 121 would prevent the '720 patent from erecting a nonstatutory double-patenting bar against the 2000/01 patents.

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Second, even assuming nonpending claims could be restricted, the Court ruled that the prosecution history in this case did not clearly document a restriction requirement, another prerequisite for § 121's statutory shield. The Court noted that the Examiner issued no document referring anywhere to "restriction." GSK argued that an interview summary evidenced a proper restriction requirement. The Court, however, found that the interview summary did not clearly set forth the subject matter and the specific claims that the PTO considered patentably distinct. Section 121 only shields claims against a double-patenting challenge if it clearly sets forth the line of demarcation between the independent and distinct inventions that prompted the restriction requirement. Because the interview summary did not clearly refer to groups of claims that the Examiner considered patentably distinct, GSK did not meet its burden in showing that the record provided a clear demarcation of the allegedly restricted subject matter.

The Court also affirmed the district court's judgment invalidating on nonstatutory double-patenting grounds two of the 1985 patents, the '352 and '552 patents, in light of the Crowley patent. The Court noted that the '352 and '552 patent claims recite limitations that are either broader than or obvious variants of correspon-

ding limitations in the Crowley claim. The Crowley patent claims pharmaceutical compositions containing "20 mg to 500 mg of potassium clavulanate [a salt of clavulanic acid]" in combination with amoxicillin, whereas the '352 and '552 patents claim pharmaceutical compositions containing a "synergistically effective amount" of clavulanic acid in combination with amoxicillin and penicillin, respectively. GSK argued that the claim limitation "synergistically effective amount" was a point of patentable distinction between the '352 and '552 patents and the Crowley patent. The Court, however, disagreed and construed the term "synergistically effective amount" to mean any amount that is synergistic against any bacteria. Because this amount encompassed a substantial part of the subject matter of the Crowley claim—namely, the "20 mg to 500 mg" range—the Court found the '352 and '552 patent claims patentably indistinct from Crowley and, thus, invalid.

Finally, the Court affirmed the district court's judgment invalidating GSK's remaining 1985 patent, the '720 patent, on nonstatutory double-patenting grounds over the Fleming patent. The Fleming patent claims a compound, potassium clavulanate, for which the written description discloses the single use of inhibiting ß-lactamase. The '720 patent claims that use as a method. The Court held that the Fleming and '720 patents are not patentably distinct because a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use.

District Court Did Not Abuse Its Discretion in Awarding Rule 11 Sanctions Against Patentee's Counsel

Steven L. Park

[Judges: Michel (author), Rader, and Newman (dissenting)]

In *Phonometrics, Inc. v. Economy Inns of America*, No. 02-1502 (Fed. Cir. Nov. 21, 2003), the Federal Circuit affirmed a sanction under Fed. R. Civ. P. 11 against a patentee's counsel for continuing to pursue infringement claims after he should have known the claims were groundless.

During the mid to late 1990s, Phonometrics, Inc. ("the patentee") sued numerous hotel companies, including Economy Inns of America (collectively "Defendants"), for infringement of U.S. Patent No. 3,769,463 ("the '463 patent"). The '463 patent relates to telephone equipment for calculating and displaying the cost of long-distance telephone calls.

The suits were stayed during the pendency of two appeals to the Federal Circuit regarding the same patent and patentee. Both appeals resulted in claim-construction rulings adverse to the patentee, the latter ruling being provided in an unpublished decision.

Based on these opinions, fourteen of the Defendants served Phonometrics with a copy of their joint (unfiled) motion for Rule 11 sanctions and a "safe-harbor" letter demanding dismissal of Phonometrics's infringement actions. In response, the patentee's counsel refused to withdraw its infringement claims and subsequently opposed the Rule 11 motion as well as the Defendants' ensuing motion for SJ. The district court granted the Rule 11 motion, personally imposing on the patentee's counsel a sanction to pay the Defendants' attorney's fees associated with bringing the sanctions motion. The district court noted that a litigant's Rule 11 obligations include a duty to refrain from continuing to advocate a position once it becomes untenable, and the patentee's continued pursuit of its claims after the Federal Circuit opinions violated that duty.

The Federal Circuit affirmed, holding that the district court did not abuse its discretion in awarding sanctions. The Court noted that each decision was on the merits since the Federal Circuit's precedential claim-construction ruling consistently applied and was resolved by that construction. The Court further noted that the patentee's counsel, who represented the patentee in virtually all the previous suits regarding the '463 patent, was very familiar with its history. Noting that the issue before the Court was not whether the Federal Circuit would award sanctions, but whether the district court abused its discretion, in view of these facts, the Court found there was ample basis for the district court's decision to impose sanctions.

Judge Newman dissented, arguing that the issue of whether the precedential claim-construction ruling applied to the Defendants

was not settled until the Federal Circuit's subsequent unpublished decision. It would be a leap, opined Judge Newman, to award Rule 11 sanctions for declining to withdraw other litigation against other parties whose infringement status was still being explored based on a non-precedential opinion.

Similarly, in *Phonometrics, Inc. v. Westin Hotel Co.*, No. 02-1501 (Fed. Cir. Nov. 26, 2003), the Federal Circuit affirmed-in-part an award of attorney's fees, but vacated part of the order and remanded for a redetermination of the amount.

Westin Hotel Company is another one of several hotel companies sued by Phonometrics. In this case, however, the grounds for the fees and costs award, in the amount of just over $24,000, were based on 35 U.S.C. § 285 and 28 U.S.C. § 1927, whereas in the above case, the fee award was based on a Rule 11 sanction.

Claim Language Requires Order for Recited Steps

Kenneth M. Lesch

[Judges: Michel (author), Mayer, and Bryson]

In *Combined Systems, Inc. v. Defense Technology Corp. of America*, No. 03-1251 (Fed. Cir. Nov. 20, 2003), the Federal Circuit affirmed the district court's SJ of noninfringement that Defense Technology Corporation of America and Federal Laboratories, Inc. (collectively "DTCA") did not infringe U.S. Patent No. 6,202,562 ("the '562 patent") assigned to Combined Systems, Inc. ("CSI") after finding no error in the district court's claim construction.

The '562 patent relates to a "tubular sock-like" shotgun projectile full of lead shot designed to incapacitate individuals without causing serious injury. The only limitations at issue in claim 1 were "forming folds in said tubular sock-like projectile body immediately forward of said rear opening" and "inserting said formed folds . . . into said projectile compartment front opening." The district court reasoned that the dictionary definition of "fold," namely, "to bend over or double up so that one part lies on another part," when combined with the gerund "forming," requires the "deliberate" and "systematic" creation of folds. The deliberate creation of folds excluded incidental gathers in the material that occur when a string is pulled to close the projectile body or when the shot is secured in the projectile compartment. Additionally, the district court held that the folds must be formed prior to, not during, insertion of the projectile into the projectile compartment.

On appeal, CSI argued that "forming folds" should be construed to mean forming any folds by closing the sock-like projectile body, including forming folds in the tail before, during, or after insertion of the projectile body into the projectile compartment. Examining the claim language first, the Federal Circuit agreed with the district court that the affirmative recitation of "forming folds" requires the "deliberate" forming of folds. The Federal Circuit also determined that as a matter of grammar, the recitation of "inserting said formed folds . . . into said projectile compartment" forecloses, in the absence of compelling intrinsic evidence to the contrary, a construction permitting the folds to be formed after or during insertion of the projectile into the projectile compartment.

The Federal Circuit then looked to the written description and drawings to determine if the presumption of ordinary and customary meaning was rebutted and to aid it in the claim-construction analysis. The written description and drawings, the Federal Circuit noted, are consistent with requiring the deliberate forming of folds and do not provide any description of incidental folds, bends, or creases. Thus, after considering the intrinsic evidence, the Federal Circuit agreed with the district court's construction requiring the deliberate forming of folds in the tail of the projectile.

CSI did not challenge the district court's conclusion that, as a matter of law, DTCA did not infringe claim 1 as construed literally or under the DOE. As a result, the Federal Circuit affirmed the district court's SJ of noninfringement.

Facts Concerning Commercial Embodiment of Invention Do Not Lead to Invalidity or Unenforceability

Won S. Lee

[Judges: Rader (author), Friedman, and Linn]

In *CFMT, Inc. v. YieldUP International Corp.*, No. 01-1452 (Fed. Cir. Nov. 12, 2003), the Federal Circuit reversed the district court's decision on inequitable conduct, vacated its SJ of invalidity for nonenablement regarding U.S. Patent Nos. 4,778,532 ("the '532 patent") and 4,917,123 ("the '123 patent"), and remanded the case for further proceedings.

The '532 and '123 patents are directed to improvements in cleaning systems for semiconductor wafers. CFMT, Inc. ("CFMT") sued YieldUP International Corporation ("YieldUP") for infringement of the '532 and '123 patents, and, in response, YieldUP asserted that the two patents were invalid for lack of enablement and unenforceable for inequitable conduct.

YieldUP's nonenablement argument was based on problems CFMT encountered in setting up an installation for Texas Instruments ("TI"). In its initial runs, the machine did not meet TI's standards for wafer cleanliness. CFMT's inventors adjusted the machine and experimented for months before meeting TI's standards. Eventually, the inventors obtained a third patent claiming the improvements in their initial machine. The district court granted YieldUP's motion for SJ that the '532 and '123 patents were invalid for nonenablement because the TI system had not cleaned wafers properly, the inventors had experimented with the system for more than six months, and the required experimentation had not been routine based on the fact that the solution to the problems had eventually resulted in the third patent.

After a bench trial, the district court entered judgment that the '532 and '123 patents were unenforceable due to inequitable conduct because: (1) CFMT did not disclose to the PTO the initial TI test results ("the TI data"), and (2) CFMT stated multiple advantages of the invention to traverse an obviousness rejection. The district court concluded that the undisclosed TI data were material because a reasonable examiner would have considered the data rebutting the invention's advantages in deciding whether to allow the two patents. The district court inferred that CFMT intended to deceive the PTO because it considered the TI data highly material.

Concerning enablement, the Federal Circuit focused on two issues: (1) whether the claims' preamble terms requiring "removal of contaminants" needed a specific level of contaminant removal that the disclosure did not enable, and (2) whether the improvements leading to the third patent showed that the '532 and '123 patents had not enabled the scope of the claimed inventions. With regard to the first issue, the Federal Circuit stated that the district court had erred in setting the enablement bar too high because enablement did not require an inventor to meet lofty standards for success in the commercial marketplace. The Federal Circuit explained that the patent statute did not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.

In the absence of any standard of cleaning in the claims, the Federal Circuit found that "cleaning" in the context of CFMT's invention meant generally removing any contaminants from the wafer surface. The Federal Circuit noted that the CFMT inventors' prototype had removed grease stains. It also pointed out that there was no evidence that a person of ordinary skill would have had to undertake undue experimentation to build a similar prototype and carry out the claimed invention to remove the contaminants, i.e., the grease stains.

The Federal Circuit noted that the lengthy experiments at TI did not show nonenablement because the CFMT inventors undertook that work to satisfy TI's particular commercial requirements, not to show enablement of the scope of the claimed inventions.

As to the district court's decision that the third CFMT patent evinced the inventors had engaged in undue experimentation to clean semiconductor wafers, the Federal Circuit stated that additional inventive work, such as an improvement invention, did not alone show nonenablement. The Federal Circuit pointed out that the district court's reasoning incorrectly

presumed that development of the third patent implied extensive experimentation because patent acquisition did not require any threshold level of effort or ingenuity.

The Federal Circuit rejected the district court's finding that the CFMT inventors' statements in response to the obviousness rejection without disclosing the TI data were inaccurate and constituted misrepresentations, because the statements listing multiple advantages of the invention were not material. The Federal Circuit noted that the statements were not inaccurate because a closed cleaning system provided an inherent advantage of less contamination by airborne particles. Since the advantages advocated in the statements recited only the natural, expected results of a closed system or at most overemphasized the benefits of the invention, the Federal Circuit concluded that this kind of advocacy did not rise to the level of misrepresentation. The Federal Circuit further noted that the Examiner had not expressly resorted to secondary considerations, such as the unexpected results and advantages in the CFMT inventors' statements, during prosecution. The Federal Circuit concluded that a reasonable Examiner would not have found the stated advantages important in deciding whether to allow the application because they were merely conclusory arguments without objective evidentiary support.

Since the TI data reflected a commercial, not statutory, standard for enablement, the Federal Circuit found that the data were only marginally relevant to the enablement issue. Contrary to the district court's finding, the Federal Circuit stated that the materiality of the undisclosed TI data was low and, therefore, the district court had little basis for inferring intent.

Since the district court erred in granting a SJ of nonenablement, the Federal Circuit vacated and remanded for the district court to reconsider whether a person of ordinary skill in the art could achieve any level of cleaning with the claimed invention without undue experimentation. Further, the Federal Circuit reversed the district court's decision on inequitable conduct because the district court had abused its discretion in view of the low materiality of the undisclosed subject matter and no evidence of intent.

Board's Decision on Obviousness Supported by Substantial Evidence

Vince Kovalick

[Judges: Schall (author), Prost, and Gajarsa (dissenting)]

In *Velander v. Garner*, No. 02-1366 (Fed. Cir. Nov. 5, 2003), the Federal Circuit affirmed the Board's decision that all allowed claims of the patent application in question were unpatentable as obvious over the prior art.

The patented technology relates to the production of nonhuman mammals that have been genetically altered so that they produce the enzyme fibrinogen in its biologically active state. The enzyme is recovered from the milk of the mammal. In an interference proceeding involving U.S. Patent Application No. 08/443,184 ("the '184 application"), the Board determined that the allowed claims were unpatentable as obvious over the prior art. The interference involved competing claims to a transgenic animal (and methods to make such an animal) that produces fibrinogen and secretes it into its milk.

After the interference was declared between the '184 application and U.S. Patent No. 5,639,940 ("the '940 patent"), Ian Garner and others (collectively "Garner") moved to have the claims in question declared unpatentable. Garner identified the elements of the claims in the prior art and contended that the motivation to combine these elements could be found in a publication by Dr. Lothar Hennighausen ("the Hennighausen review") and in U.S. Patent No. 4,873,316 ("the Meade patent"). Garner contended that the Meade patent disclosed a method for the production of heterologous proteins in the milk of transgenic animals, while the Hennighausen review suggested the production of commercial quantities of plasma proteins in transgenic animals, and, therefore, fibrinogen was an obvious target for expression in transgenic animals.

Applicant, Velander, did not dispute that the elements of the claims were in the prior art nor that the prior art contained some motivation to combine those elements. Rather, he argued that, given the variables that affect protein expression levels, as of the critical date, one of ordinary skill in the art would not have had a

reasonable expectation of success in practicing the invention claimed. Velander asserted that the Board improperly placed on him the burden of proving an expectation of failure in the prior art rather than requiring Garner to prove a reasonable expectation of success to substantiate obviousness. The Federal Circuit dismissed this argument, however, observing that the Board clearly understood the burdens and applied them appropriately.

The Federal Circuit reviewed the conflicting expert testimony submitted by declarations from both parties and concluded that, although this was a close case, substantial evidence supported the Board's decision. The Court summarized the case as boiling down to the question of whether, as of the critical date, one of ordinary skill in the art would have had a reasonable expectation of success in producing a recoverable amount of biologically active fibrinogen from a transgenic, nonhuman female mammal that produces recoverable amounts of biologically active human fibrinogen in its milk. Given all the evidence, the Court could not say that Velander had established that the Board's decision was not supported by substantial evidence. Although other evidence in the record supported Velander's argument, the Federal Circuit ruled that if the evidence supports several reasonable but contradictory conclusions, it will not find the Board's decision unsupported by substantial evidence simply because the Board chose one conclusion over another plausible alternative.

Judge Gajarsa dissented, concluding that there was no reasonable basis for the Board's decision and that the finding of obviousness lacked substantial evidence.

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