

Last month at

The Federal Circuit



FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

Washington, DC
202.408.4000

Atlanta, GA
404.653.6400

Cambridge, MA
617.452.1600

Palo Alto, CA
650.849.6600

Reston, VA
571.203.2700

Brussels
+ 32 2 646 0353

Taipei
+ 886 2 2712 7001

Tokyo
+ 03 3431 6943

EDITED BY VINCE KOVALICK

ANDA FILING FOR UNPATENTED USE OF UNAPPROVED DRUG IS NOT COGNIZABLE ACT OF INDUCED INFRINGEMENT

A method of use patent holder may not sue an ANDA applicant for induced infringement of its patent if the ANDA applicant is not seeking FDA approval of the use claimed and the use claimed is not FDA-approved. *Allergan, Inc. v. Alcon Labs., Inc.*, No. 02-1449 (Fed. Cir. Mar. 28, 2003)1

INDUSTRY PRACTICE CONSIDERED TO ASSESS OFFER FOR SALE UNDER ON-SALE BAR

Court should consider industry practice to determine whether commercial activity of patentee constitutes an offer for sale that creates an on-sale bar under § 102(b). *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, No. 01-1371 (Fed. Cir. Mar. 13, 2003)1

PATENT SPECIFICATION DEFINES CLAIM TERM DESPITE ALLEGED ORDINARY MEANING

Where the patentee has chosen to be his own lexicographer, the district court did not err by reading the patentee's definition from the specification into the claim. *Abbott Labs. v. Novopharm Ltd.*, No. 02-1387 (Fed. Cir. Mar. 20, 2003)3

INVENTORS' MISREPRESENTATIONS LEAD TO INEQUITABLE CONDUCT

Court affirms some findings of inequitable conduct based on inaccurate scientific statements made in patent and during patent prosecution, but remands case for consideration of intent issues and unenforceability. *Hoffmann-La Roche, Inc. v. Promega Corp.*, No. 00-1372 (Fed. Cir. Mar. 31, 2003) . . .3

"ADMISSION" OF PRIOR ART NOT NECESSARILY BINDING

One's own work may not be considered prior art in the absence of a statutory basis, and a patentee should not be punished for being as inclusive as possible and referencing his own work in an IDS. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, No. 02-1030 (Fed. Cir. Mar. 31, 2003)5

SSL SATELLITE DOES NOT INFRINGE UNDER DOE BECAUSE OF "ALL ELEMENTS" RULE

In the absence of an element that performs the properly construed functions of a means-plus-function limitation, a finding of infringement under DOE would entirely vitiate the limitations. *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, No. 00-1310 (Fed. Cir. Mar. 24, 2003)5

UNIVERSITY OF NEW MEXICO OWNS PATENTS FOR CANCER TREATMENT COMPOUNDS

When a state files suit in federal court to enforce its claims to certain patents, the state shall be considered to have consented to have litigated in the same forum all compulsory counterclaims, i.e., those arising from the same transaction or occurrence that gave rise to the state's asserted claims. *Regents of the Univ. of N.M. v. Knight*, No. 02-1018 (Fed. Cir. Feb. 28, 2003)6

CLAIM CONSTRUCTION UNDER 35 U.S.C. § 112, ¶ 6 FOUND UNDULY RESTRICTIVE

For means-plus-function limitation, features that do not perform the recited function do not constitute corresponding structure. *Northrop Grumman Corp. v. Intel Corp.*, No. 02-1024 (Fed. Cir. Mar. 31, 2003)8

CLAIM PREAMBLE LIMITATION "REVERSES" INFRINGEMENT FINDING ON GEAR SHIFT PATENT

When claim drafter chooses to use both the preamble and the body of a claim to define the subject matter of the invention, the invention so defined is the one the patent protects. *Eaton Corp. v. Rockwell Int'l Corp.*, No. 01-1633 (Fed. Cir. Mar. 27, 2003)9

PRIOR ART RENDERS METHOD FOR VIBRATING ZEBRA MUSSELS TO DEATH UNPATENTABLE

Under 35 U.S.C. § 145, newly presented evidence after appeal of a Board decision requires de novo fact-finding by district court and review for clear error by Federal Circuit. *Mazzari v. Rogan*, No. 02-1269 (Fed. Cir. Mar. 17, 2003)10

TISSUE DISSECTION PATENT INVALID

The absence of a requirement to leave a tissue expander in place is not a teaching to remove it. *Williams v. General Surgical Innovations, Inc.*, No. 02-1474 (Fed. Cir. Mar. 7, 2003) (nonprecedential decision)10

ANDA Filing for Unpatented Use of Unapproved Drug Is Not Cognizable Act of Induced Infringement

Deborah Katz

[Judges: Clevenger, Schall, and Linn (per curiam)]

In *Allergan, Inc. v. Alcon Laboratories, Inc.*, No. 02-1449 (Fed. Cir. Mar. 28, 2003), the Federal Circuit affirmed the district court's grant of SJ in favor of Defendants, Alcon Laboratories, Inc. ("Alcon") and Bausch & Lomb, Inc. ("B&L"). While the Federal Circuit relied on different reasoning than the district court, it agreed that there was not sufficient basis for inducing infringement under 35 U.S.C. § 271(e)(2) due to the filing of Defendants' ANDAs, which did not recite the patented methods of use.

Allergan, Inc. ("Allergan") sells a compound, brimonidine, as a drug for treatment of open-angle glaucoma, a condition that causes damage to optical cells, presumably by increased intraocular pressure. Brimonidine is not a patented compound, though its use to reduce the intraocular pressure associated with glaucoma is approved by the FDA. After further research, Allergan discovered that brimonidine is also effective in treating patients with neurodegeneration of the optic nerve, even if they do not have increased intraocular pressure. Allergan obtained two patents on the use of brimonidine to treat neurodegeneration. Subsequently, Alcon and B&L filed ANDAs in the FDA to market generic versions of brimonidine for reducing intraocular pressure, but not for the methods claimed in Allergan's patents.

Allergan proceeded with this suit under a theory of induced infringement under 35 U.S.C. § 271(e)(2), contending that if Alcon and B&L obtained approval for their ANDA for use of brimonidine to reduce intraocular pressure, they would then encourage doctors to also use brimonidine to reduce neurodegeneration. Alcon and B&L countered that there would be no infringement because their ANDAs were filed for a use that was not patented.

The district court granted SJ, finding that the filing of an ANDA is not sufficient for a claim of induced infringement under 35 U.S.C. § 271(e)(2), because claims under that statute can only be claims that are excluded under the exemptions of 35 U.S.C. § 271(e)(1). In addition, the district court found a lack of controversy in the induced infringement cause of action because no third party had directly infringed Allergan's patents yet.

On appeal, the Federal Circuit found that the issue was decided in *Warner Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), where the

Court ruled that it was not an act of infringement to submit an ANDA for the use of a drug when neither the intended use is claimed in the patent-in-suit, nor the patented use is approved by the FDA. In reaching its decision, the Court explained that infringement under 35 U.S.C. § 271(e)(2) is not merely jurisdictional, but reflects Congress's intent that filing of an ANDA is an act of infringement, which is then subject to the other determinations of infringement found elsewhere in the statute. The Court concluded that while a § 271(e)(2) induced infringement claim may be speculative, it is not sufficiently so to contravene the case or controversy requirement. Although no third party may have directly infringed the patents, the Court found that Congress's intent to extend infringement to acts by the ANDA filer before the generic drug was even marketed surmounted any constitutional hurdle for a lack of case or controversy.

Nevertheless, the Federal Circuit affirmed the SJ of noninfringement because the patents-in-suit protected only methods of use that were not approved by the FDA and, therefore, not a part of Alcon's and B&L's ANDAs, given the *Warner Lambert* precedent.

Judge Schall, joined by Judge Clevenger, wrote a concurring opinion because of the Court's precedent in *Warner-Lambert*, but disputed the holding of that case. These judges commented that Congress's intent in drafting 35 U.S.C. § 271(e)(2) was to allow for an infringement suit for the filing of an ANDA when there was sufficient evidence that the filer would encourage any use of an approved drug that is claimed in a patent, not just the FDA-approved uses. Writing separately, Judge Linn concurred because of the holding of *Warner-Lambert*, but stated that the *Warner-Lambert* Court had overstepped its bounds in interpreting Congress's intent by making policy decisions that were not apparent in the plain language of the statute.

Industry Practice Considered to Assess Offer for Sale Under On-Sale Bar

Andrew J. Vance

[Judges: Michel (author), Newman (concurring-in-part and dissenting-in-part), and Clevenger (dissenting-in-part)]

In *Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.*, No. 01-1371 (Fed. Cir. Mar. 13, 2003), the Federal Circuit affirmed-in-part and vacated-in-part the district court's judgment and then remanded the case for further proceedings.

Lacks Industries, Inc. ("Lacks") sued McKechnie Vehicle Components USA, Inc. ("McKechnie") and

Hayes Wheel International, Inc. (“Hayes”) for infringement of U.S. Patent Nos. 5,577,809 (“the ‘809 patent”), 5,636,906 (“the ‘906 patent”), and 5,597,213 (“the ‘213 patent”), which cover various aspects of cladding for automobile wheels. Wheel cladding is a plastic or metal skin that fits over the outer face of a wheel to provide a chrome-like appearance on a wheel at less cost than plating the entire wheel.

Prior to trial, the district court granted SJ of (1) noninfringement of the asserted claims of the ‘809 and ‘906 patents; (2) invalidity of claims 1, 3, and 8 of the ‘213 patent; and (3) invalidity of the asserted claims of the ‘809 and ‘906 patents. By agreement, the remaining infringement and validity issues for the ‘213 patent were tried by a SM, who found claims 11-13, 20, 24, and 25 literally infringed, but who also found these same claims and claims 21 and 22 invalid. The district court adopted the SM’s findings in their entirety and entered judgment accordingly.

On appeal, Lacks argued that the district court had based its SJ of noninfringement of the ‘809 and ‘906 patents on an improper interpretation of the claim terms “axial peripheral lip” and “wheel face outer surface.” Relying on dictionary definitions and the prosecution history, Lacks argued that the district court had construed the claims too narrowly. Affirming the district court’s SJ of noninfringement, however, the Federal Circuit rejected Lacks’s proposed interpretation, holding that the weight of the intrinsic evidence supported the district court’s interpretation. The Federal Circuit observed that Lacks’s proposed construction of “axial peripheral lip” was inconsistent with the patent drawings and that its proposed construction of “wheel face outer surface” was inconsistent with the plain language of the claims.

McKechnie and Hayes cross-appealed the district court’s finding that they literally infringed claims 11-13, 20, 24, and 25 of the ‘213 patent, arguing that their products did not satisfy a limitation requiring adhesive to “permanently secure” the cladding to the wheel. The district court held that this limitation required the adhesive itself to be capable of securing the cladding to the wheel. Although not disputing the district court’s claim interpretation, the cross appellants argued that the SM had erred by adopting an infringement test that impermissibly read out the requirement that the adhesive secure the cladding by itself. The cross appellants also argued that the evidence of record was insufficient to find infringement under the SM’s infringement test. Rejecting these arguments, the Federal Circuit held that the SM’s infringement test

was proper and that there was sufficient evidence to support the infringement findings. Judge Clevenger dissented, agreeing with the cross appellants that the evidence of record was insufficient.

Turning to validity, the Federal Circuit vacated the SJ of invalidity of the ‘809 and ‘906 patents since McKechnie and Hayes raised invalidity only as an affirmative defense and the Court affirmed the SJ of noninfringement. Citing *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), the Federal Circuit observed that it need not reach validity issues under such circumstances.

Lacks also appealed the district court’s SJ of invalidity of claims 1, 3, and 8 of the ‘213 patent, which held the claims anticipated by Lacks’s own published foreign patent application under the statutory bar of § 102(b). Rejecting Lacks’s contention that its foreign applications did not disclose all of the claim limitations, the Federal Circuit affirmed the district court’s invalidity decision. Judge Newman dissented from this aspect of the decision, arguing that, in her view, an inventor’s own published foreign application should not constitute a statutory bar to the inventor’s U.S. application.

Additionally, Lacks appealed the district court’s SJ of invalidity of claims 11-13, 20-22, 24, and 25 of the ‘213 patent, which held that Lacks’s sales promotion activities prior to the critical date created an on-sale bar under § 102(b). Lacks disagreed with the district court’s holding that it had made a “commercial offer for sale,” arguing that the district court had applied the wrong legal standard. The Federal Circuit ruled that sales promotional activity must rise to the level of a commercial offer for sale, as defined by contract law, to constitute an on-sale bar. Since the district court’s standard did not require a formal offer for sale under contract law, the Federal Circuit vacated the district court’s invalidity decision and remanded it for consideration under the proper standard, suggesting that the district court consider additional evidence of industry practice. In dissenting, Judge Newman argued that the proper standard for determining an offer should not include analysis of industry practice.

Finally, McKechnie and Hayes cross-appealed the district court’s findings that their own activities, prior to the critical date, did not give rise to a § 102(b) statutory bar, because the cross appellants failed to introduce sufficient evidence to corroborate such activities. The cross appellants argued that the district court had erred by refusing to permit oral testimony of one witness to corroborate oral testimony of another and by finding their documentary evidence insufficient to corroborate the

oral testimony. Affirming the district court's findings, however, the Federal Circuit noted that oral testimony of interested witnesses requires documentary corroboration and concluded that the SM's findings that the cross appellants' documentary evidence failed to corroborate the oral testimony were thorough.

Patent Specification Defines Claim Term Despite Alleged Ordinary Meaning

Gordon P. Klancnik

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

In *Abbott Laboratories v. Novopharm Ltd.*, No. 02-1387 (Fed. Cir. Mar. 20, 2003), the Federal Circuit affirmed the lower court's grant of SJ of non-infringement.

U.S. Patent No. 4,895,726 ("the '726 patent") claims a composition and methods relating to therapeutic fenofibrate, which can be used to treat hyperlipidemia or hypercholesterolemia. After Novopharm Ltd. ("Novopharm") filed an ANDA seeking approval to market a generic fenofibrate, the assignee of the '726 patent and its exclusive licensee, Abbott Laboratories ("Abbott"), filed suit under the provisions of the Hatch-Waxman Act. Abbott holds the approved New Drug Application for fenofibrate and markets fenofibrate as TRICOR®.

Whether Novopharm's generic fenofibrate would infringe if approved by the FDA hinged on the construction of the term "co-micronization," which appeared in both of the asserted independent claims and was added during prosecution. Abbott argued that the plain meaning of the disputed claim term should control, but the Federal Circuit disagreed.

In particular, the Court explained that claim terms are generally accorded their ordinary and accustomed meaning, except where the patentee clearly defines a term in the specification. Here, the '726 patent explicitly defines "co-micronization" as an "intimate mixture of fenofibrate and a solid surfactant," and, thus, the claim term excluded mixtures including ingredients, such as excipients and water, in addition to the intimate mixture of fenofibrate and a surfactant. Because Novopharm's process will not "co-micronize" fenofibrate and a solid surfactant, there will be no literal infringement. The Court further ruled that Novopharm's process will not infringe under the DOE, as that would vitiate the step of "co-micronization" in contravention of the all-elements rule.

Inventors' Misrepresentations Lead to Inequitable Conduct

Won S. Lee

[Judges: Bryson (author), Archer, and Newman (dissenting)]

In *Hoffmann-La Roche, Inc. v. Promega Corp.*, No. 00-1372 (Fed. Cir. Mar. 31, 2003), the Federal Circuit sustained certain findings of inequitable conduct but vacated the district court's order of unenforceability and remanded for further consideration of the unenforceability holding given the Court's ruling.

Cetus Corporation ("Cetus"), the predecessor of Hoffmann-La Roche, Inc. and Roche Molecular Systems, Inc. (collectively "Roche"), filed U.S. Patent Application No. 07/063,509 ("the '509 application"), which was directed to a purified thermostable enzyme that could be used in polymerase chain reaction ("PCR"). During its prosecution, the '509 application was rejected on various grounds, including anticipation/obviousness based on two journal articles, both of which disclosed a DNA polymerase derived from the *Thermus aquaticus*, or "Taq" bacterium, which is stable and active at high temperatures.

In response, the inventors entered new claims reciting purified thermostable Taq DNA polymerase having a specific molecular-weight range. They also made a two-part argument for patentability: (1) the claimed enzyme was distinct from the prior art enzyme, citing differences in molecular weight, specific activity, and fidelity; and (2) the claimed enzyme was far more pure than the prior art enzyme. Thereafter, the '509 application issued as U.S. Patent No. 4,889,818 ("the '818 patent").

Cetus licensed the '818 patent to Promega Corporation ("Promega") and later sold it to Roche. Roche sued Promega, alleging breach of the license agreement. Promega counterclaimed, asserting that the '818 patent was unenforceable due to inequitable conduct. After a bench trial, the district court held that the '818 patent was unenforceable based on (1) misrepresentations regarding the difference in molecular weight between the claimed and prior art Taq enzymes; (2) misrepresentations that the inventors had performed Example VI, one of the procedures described in the specification, and that they had achieved the described results; and (3) misrepresentations concerning the comparative fidelity of the claimed enzyme and the prior art enzymes.

During the prosecution of the '509 application, the inventors argued that the claimed enzyme with a molecular weight of 86,000 to 90,000 daltons

was different from the prior art enzymes with molecular weights of 60,000 to 68,000 daltons, which they believed, at most, had been a crude preparation of degraded Taq polymerase. One issue over the disparity in molecular weights related to one inventor's experiment where she observed that a Taq fragment with a molecular weight of 62,000 daltons did not bind to a phosphocellulose column. In the district court's view, the fact that the Taq fragment did not bind to the phosphocellulose column indicated that a similar fragment would have been lost in the prior art experiment, because that experiment also used the same material. The district court concluded that the experiment suggested that the prior art enzymes were not simply degraded fragments of Taq polymerase and the inventors withheld that information from the PTO. The Federal Circuit disagreed because the experiment had been conducted under salt conditions (80 mM) very different from those described in the prior art reference (10 mM), which was critical to the capacity of the fragment to bind to the column. Since the results of the experiment were not pertinent to the inventors' characterization of the prior art enzyme, the Federal Circuit held that the experiment was not material and the inventors had no intent to deceive.

The district court also ruled that the inventors improperly withheld information that suggested that the prior art technique was inaccurate and produced results underestimating the true molecular weight, which could weaken the inventors' argument that the claimed enzyme was distinct from the prior art enzyme. The Federal Circuit reversed the district court's ruling because none of the cited information suggested that the inventors knew the defects of the prior art technique.

The next issue was directed to Example VI of the '509 application, which was a procedure for repeatedly refining, or fractionating, a bacterial culture of the Taq enzyme through a variety of techniques, including column chromatography, thereby producing a purified version of the claimed enzyme. The Federal Circuit noted that Example VI was written in the past tense, suggesting that the test had been performed, but agreed that the test had not been performed as written in light of the testimony adduced at trial.

Roche also suggested that the use of the past tense in Example VI was not really a misrepresentation since all of the steps in that procedure had in effect been performed through the combination of two preparatory steps, Prep 3 and Prep 4, which Roche had actually performed. However, Roche offered no evidence contradicting Promega's argument that the results of Prep 3 and Prep 4 would not provide an accurate representation of the

results of a procedure conducted according to Example VI.

The Federal Circuit found intent because the inventors had attested that all statements in the '509 application had been true and Roche had not introduced any other evidence explaining why the past tense had been used to describe an experiment that had not been performed.

Roche also argued that because the '818 patent did not include claim limitations directed to purity, representations about purity made in the application could not be material. The Federal Circuit, however, found the information regarding Example VI material because the purity results reported in Example VI and the reference to them in the office action response had been central enough to the prosecution to be within a reasonable examiner's realm of consideration.

The last issue was directed to the inventors' representation that their claimed enzyme exhibited high fidelity compared to the prior art enzyme. The Federal Circuit upheld the district court's finding that the statements characterizing the activity of the prior art enzymes and comparing it to that of the claimed enzyme were inaccurate because Promega's expert witness testified that the differing results related to differences in experimental conditions and not to differences in the properties of the enzymes. Roche argued that the inventors and the expert simply differed over how to interpret the results of the experiments involving the prior art and claimed enzymes, and that a dispute of that sort could not give rise to a finding of inequitable conduct. The Federal Circuit disagreed and noted that Roche failed to make a persuasive showing that there was a legitimate difference of scientific opinion on that issue.

The Federal Circuit upheld the district court's finding of materiality with respect to the fidelity issue because the fidelity statement in the office action response had been made in an effort to support the inventors' primary argument for patentability—that the claimed enzyme was different from the prior art enzyme, even though the most prominent evidence cited by the inventors in this regard was a difference in molecular weight. The Federal Circuit also supported the district court's finding that the statements about fidelity were intentionally deceptive, based primarily on expert testimony that one inventor had knowledge of the fidelity issue and could not possibly have believed that the experiments indicated that the prior art enzyme was promiscuous and inferior in fidelity.

The Federal Circuit vacated the finding of inequitable conduct, however, and stressed that the district court must now determine whether the

material misrepresentations or omissions in question were sufficiently serious in light of the evidence of intent to deceive, under all the circumstances, to warrant the severe sanction of holding the patent unenforceable. Since the district court had not expressly addressed this determination, and the Federal Circuit did not uphold all of the grounds on which the district court had found inequitable conduct, the Federal Circuit vacated the district court's unenforceability order and remanded the case for further proceedings.

Judge Newman dissented, concluding that the majority had expanded the substantial grounds of inequitable conduct by finding misrepresentations in correct science, inferring malevolence from verb tense, and grounding intent to deceive on personal slurs by a hostile witness.

"Admission" of Prior Art Not Necessarily Binding

Benjamin D. Wiese

[Judges: Linn (author), Clevenger, and Schall]

In *Riverwood International Corp. v. R.A. Jones & Co.*, No. 02-1030 (Fed. Cir. Mar. 31, 2003), the Federal Circuit vacated the district court's holding that Riverwood International Corporation's ("Riverwood") U.S. Patent No. 5,241,806 ("the '806 patent") is prior art by admission, vacated the district court's judgment that certain claims of Riverwood's U.S. Patent Nos. 5,666,789 ("the '789 patent") and 5,692,361 ("the '361 patent") are invalid as obvious, and affirmed the district court's judgment that the '789 and '361 patents are infringed.

Riverwood is the owner of the '806, '789, and '361 patents ("patents-in-suit"), which are directed to packaging methods and machines. Riverwood filed suit against R.A. Jones & Co. ("Jones"), alleging that Jones's cartoning machines infringed certain claims of the patents-in-suit. Jones counterclaimed, alleging invalidity.

During prosecution of the '789 and '361 patents, Riverwood's attorney filed an Information Disclosure Statement ("IDS") listing the '806 patent as "prior art." Jones argued that this transformed the '806 patent into prior art by admission. In the alternative, Jones argued that the '806 patent is prior art under 35 U.S.C. § 102(e). Riverwood argued that a common inventor developed the portion of the particular embodiment of the '806 patent that formed the relevant disclosure and claims for the '789 and '361 patents. Prior to trial, the district court held that the '806 patent was prior art by admission and could be presented as such to

the jury during trial. The jury found that Jones infringed certain claims of the '789 and '361 patents, and also found all asserted claims of the '789 and '361 patents invalid as obvious.

On appeal, the Federal Circuit ruled that one's own work may not be considered prior art in the absence of a statutory basis, and a patentee should not be punished for referencing his own work in an IDS. The Court thus determined that the '806 patent, if issued to the same inventive entity, is not prior art regardless of the admission. Likewise, the Court determined that the '806 patent is not prior art under 35 U.S.C. § 102(e) if issued to the same inventive entity, as the statute requires that the reference at issue must be "by another." The patents-in-suit, however, were not issued to the same inventive entity. What is significant, according to the Court, is not merely the differences in the listed inventors, but whether the portions of the reference relied on as prior art and the subject matter of the claims in question represent the work of a common inventive entity. The Court accordingly vacated the district court's holding that the '806 patent is prior art and its judgment of invalidity, and remanded for appropriate findings.

Turning to the issue of infringement, the Federal Circuit found that the district court had not erred in its construction of the term "flight bars" to include a plurality of structures. Jones argued that the district court had erred by not limiting the term "flight bars" to a unitary structure. None of the patents-in-suit explicitly defines the term, nor is the term found in any dictionary or treatise. The Court found nothing in the claim language, specification, or prosecution history that is inconsistent with the district court's construction. Jones also argued that the district court had improperly relied on extrinsic evidence, including expert testimony from another case involving the same patents. The Federal Circuit did not find this reliance improper, as the extrinsic evidence did not contradict the claim language or the import of the specification.

SSL Satellite Does Not Infringe Under DOE Because of "All Elements" Rule

Anthony J. Lombardi

[Judges: Gajarsa (author), Schall, and Friedman]

In *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, No. 00-1310 (Fed. Cir. Mar. 24, 2003), on remand from the Supreme Court, the Federal Circuit affirmed the district court's grant of SJ of noninfringement based on new grounds.

Lockheed Martin Corporation ("Lockheed") is the assignee of U.S. Patent No. 4,084,772 ("the

'772 patent"), which discloses an apparatus and method for steering a satellite. Lockheed's predecessor, Martin Marietta Corporation, previously brought a patent-infringement action against Space Systems/Loral, Inc. ("SSL"), alleging that certain SSL satellites infringe the '772 patent.

Typically, a communications satellite orbits the earth in a geosynchronous equatorial orbit, which allows the satellite to maintain the same position relative to fixed points on the earth's surface. However, while in orbit, a satellite is subject to various destabilizing forces, such as the gravitational effects of the sun and the moon. These forces may cause a satellite to drift out of its equatorial orbit and into an inclined north-south orbit. The system disclosed in the '772 patent allows a satellite to continue to operate effectively after entering an inclined orbit. It does so by changing the attitude, or pointing direction, of the satellite when the satellite is north and south of the equator so that the satellite remains pointed at the same earth target. This change is accomplished by a momentum wheel, which spins to create angular momentum, much like a gyroscope, to keep the satellite pointed in the proper direction.

The intentional adjustment of the satellite, however, creates a control problem. Prior art satellites use an earth horizon or roll sensor to keep the satellite pointed at the center of the earth during equatorial orbit. If the sensor determines that the satellite is not pointed at the center of the earth, it activates a roll thruster to reorient the satellite. During inclined orbit, however, the satellite is intentionally rotated away from the center of the earth. In addressing this problem, the structure and method disclosed in the '772 patent causes the sensor to ignore this intentional rotation by generating a signal, which represents the angle of intentional roll, and subtracting it from the signal generated by the sensor.

Claim 1 of the '772 patent recites, in part, "means for rotating said wheel in accordance with a predetermined rate schedule which varies sinusoidally over the orbit at the orbital frequency of the satellite." The district court construed the phrase "varies sinusoidally" to mean "a sine-shaped variation that passes through zero." The Federal Circuit then affirmed the district court's decision on the ground that its *Festo* decision barred the application of the DOE because the limitation had been amended. However, following the Supreme Court's review of *Festo*, the Supreme Court remanded the case to the Federal Circuit for further consideration.

On remand, Lockheed contended that a factual dispute existed as to whether the SSL satellites met the requirements of the claim language under the DOE. Lockheed argued that the speed of the SSL wheel varies sinusoidally even though it is always spinning faster than a set bias speed. The Federal

Circuit, however, considered whether the scope of the DOE was proscribed by the all-elements rule.

The Federal Circuit concluded that it was undisputed that the speed of the SSL wheel does not slow to zero, stop, and reverse direction twice during each orbit of its operation, as is required by the proper construction of the phrase "varies sinusoidally over the orbit at the orbital frequency." Further, the claim language requires the SSL wheel to vary according to a "predetermined rate schedule." The SSL satellite, however, does not use a predetermined rate schedule. Because the accused satellite lacks an element that performs these properly construed functions, a finding of infringement under the DOE would entirely vitiate these limitations. Therefore, the Federal Circuit affirmed the district court's grant of SJ in favor of SSL.

University of New Mexico Owns Patents for Cancer Treatment Compounds

Kakoli Caprihan

[Judges: Lourie (author), Newman, and Schall]

In *Regents of the University of New Mexico v. Knight*, No. 02-1018 (Fed. Cir. Feb. 28, 2003), the Federal Circuit affirmed-in-part, reversed-in-part, and vacated-in-part the district court's rulings concerning ownership of several patents and applications relating to beta-alethine compounds and vitaletheine. Drs. Galen Knight and Terence Scallen served respectively as a faculty staff member and a professor of biochemistry at the University of New Mexico ("UNM"). While employed by UNM, they, along with an additional faculty member, invented the cancer compounds disclosed. In 1990, UNM filed patent applications based on those compounds. A year later, the inventors assigned the applications to UNM and signed a UNM Co-Inventor Agreement relating to the vitaletheine inventions. In 1992, UNM filed continuation-in-part ("CIP") applications from each of the previously filed parent applications. However, Scallen and Knight never assigned any of the CIP applications to UNM.

In 1994, UNM entered into a license agreement with Dovetail Technologies, Inc. ("Dovetail"), in which UNM warranted its ownership of the patents and applications related to the compounds. Dovetail, through another company, then attempted to synthesize the compounds and found that they could not be made according to the patent disclosure. UNM retained two scientists to synthesize the compounds, and they determined that the structures were inaccurate and ascertained the cor-

rect structures of the compounds. UNM then submitted amendments changing the structures of the compounds. Scallen and Knight objected to the changes, but the PTO accepted them.

In 1999, Dovetail notified UNM that it was in breach of the warranty of ownership provision of their license agreement. Subsequently, UNM filed suit against Scallen and Knight, seeking ownership of the patents and applications, correction of inventorship, alleged breach of the UNM Intellectual Property Policy and the Co-Inventor Agreement, and other state law claims. Scallen and Knight, acting pro se, filed counterclaims against UNM.

The district court appointed a SM to evaluate the case and make recommendations. The SM found that Scallen and Knight were obligated to assign the beta-alethine patents and applications, based on a review of the 1983 UNM Patent Policy and the 1991 Joint Assignments, and the fact that the inventors had also signed powers of attorney and claimed small-entity status during the initial patent and CIP filings. The SM also found that the Appellants had breached their agreements with UNM by not executing assignments of the beta-alethine patents and applications. The district court adopted the recommendations and entered SJ on the counts related to the ownership of the beta-alethine patents/applications and breach of UNM's policies relating to intellectual property. The district court then determined that the compounds described in the parent and CIP applications were inherently the same structures found in the amendments and relied on the PTO's decision that the amendments did not introduce new matter. The district court also granted UNM's motion to amend its complaint and withdraw any request for money damages. Additionally, the district court held that UNM, as an arm of the state, had not waived its Eleventh Amendment immunity because UNM's amended complaint no longer sought any money damages.

The Federal Circuit affirmed the lower court's grant of SJ that Scallen and Knight had breached their contractual obligation to assign their patents and applications to UNM. The Court ruled that state law governs contractual obligations and transfers of property rights, including those relating to patents. In this case, the Court applied New Mexico state law to UNM's breach of contract claim. As a faculty member, Scallen entered into a written employment contract with UNM, which incorporated the 1983 Patent Policy. Knight, as a faculty staff member, did not enter into an employment contract with UNM; however, under New Mexico law, a written personnel policy may form an implied employment contract. The Patent Policy provided that staff members whose inventions and

discoveries were made using UNM's resources, belong to UNM. Also, each staff member who makes such an invention has a duty to cooperate fully with UNM and this cooperation includes the signing of patent applications and associated documents. The Co-Inventor Agreement contains similar language regarding cooperation in preparation of patent applications, etc. Additionally, the Joint Assignment agreements require Scallen and Knight to sign all lawful papers to execute all applications. The Court determined that the inventions belong to UNM and Scallen and Knight were under a duty to cooperate in prosecution of patent applications dealing with those inventions and to assign their inventions and all related patents and applications, including the CIP applications. The Court also found that Scallen and Knight had conducted themselves as though they were obligated to assign their inventions for several years, until a dispute broke out.

Scallen and Knight argued that they are not the inventors of the subject matter of the invention since UNM allegedly added new matter to the CIP applications. However, the Federal Circuit found that there was no new matter added to the applications since the amendments did not describe new inventions, but just clarified and corrected the incorrect characterization of the already disclosed invention.

Thus, Scallen and Knight were contractually obligated to assign the patents and applications to UNM, and UNM is the rightful owner of the beta-alethine patents and applications.

The Federal Circuit also found that the district court did not abuse its discretion in permitting amendment of the complaint, but reversed the lower court's dismissal of Scallen's and Knight's counterclaims for money damages as being barred under the Eleventh Amendment. In ruling on this issue, to promote national uniformity in the application of the patent law, the Federal Circuit found that the question of Eleventh Amendment waiver is a matter of Federal Circuit law. The Court found that such a waiver occurs when a state voluntarily appears in federal court and, therefore, waives its immunity for all compulsory counterclaims. Compulsory counterclaims arise from the same transaction or occurrence and are not strictly for the same kind or nature, but are those that should be litigated together. Accordingly, the Court held that when UNM (a state entity) filed suit in federal court to enforce its claims to certain patents, it waived its Eleventh Amendment immunity with respect to compulsory counterclaims arising from those contracts and conduct.

Claim Construction Under 35 U.S.C. § 112, ¶ 6 Found Unduly Restrictive

Brett G. Alten

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

In *Northrop Grumman Corp. v. Intel Corp.*, No. 02-1024 (Fed. Cir. Mar. 31, 2003), the Federal Circuit reversed the district court's judgment of noninfringement of a patent for a serial bus interface unit and remanded the case on the ground that the district court had erred in its claim construction.

Northrop Grumman Corporation ("Northrop") is the assignee of U.S. Patent No. 4,453,229 ("the '229 patent"), entitled "Bus Interface Unit." In late 2000, Northrop filed suit in the United States District Court for the Eastern District of Texas against several Defendants (collectively "3Com"), alleging that the Defendants had infringed several claims of the '229 patent.

The district court adopted a SM's recommendations with regard to three claim construction issues and ruled in the Defendants' favor on the issue of infringement. The district court subsequently entered a final judgment under Fed. R. Civ. P. 54(b), and Northrop appealed.

Claims 1 and 13 are directed to a bus interface unit that supervises the exchange of data between a host computer and a network serial bus. Both claims included, in essentially identical form, "means for monitoring" and "means for defining." Northrop argued that the district court had erroneously construed those two limitations, as well as the term "bus interface unit," by interpreting each of them as limited to devices employing a command/response protocol.

The Federal Circuit agreed that the district court had properly determined that the "means for monitoring," recited in claims 1 and 13, performs two functions: "monitoring a plurality of logical signals characterizing the operational status of the bus interface unit" and "generating a plurality of control signals regulating a data transfer process." The Court also agreed that the written description made clear that certain sequence logic performed the monitoring and generating functions, and that the structures within the sequence logic include, at a minimum, an AND array, an OR array, and a number of flip-flops.

The Federal Circuit disagreed, however, that additional elements were also required as part of the corresponding structure, even though the district court had identified those additional elements as directly tied to the claimed functions. The

Federal Circuit acknowledged that under 35 U.S.C. § 112, ¶ 6, structure disclosed in the specification is corresponding structure only if the specification or the prosecution history clearly links or associates that structure to the function recited in the claim. Features that do not perform the recited function do not constitute corresponding structure and, thus, do not serve as claim limitations. Thus, the Federal Circuit concluded that the additional elements identified by the district court could not be part of the structure corresponding to the functions of the "means for monitoring" limitation because they concerned other functions.

Next, the Federal Circuit considered the limitation "means for defining a functional state of the bus interface unit." The district court had previously held that the function of the "means for defining" is to define the functional state of the bus interface unit, and concluded that such function requires, at a minimum, determining whether the bus interface unit is functioning in the bus controller or remote terminal mode. The district court had also determined that this necessarily involved monitoring an operating mode signal and identified the corresponding structure, including, at a minimum, an AND array, an OR array, the operating mode signal, and flip-flops of the state register necessary to define the bus interface unit as functioning in either a bus controller or remote terminal mode, and any equivalents thereof.

As in the case of the "means for monitoring" limitation, the Federal Circuit ruled that the district court had defined the structure corresponding to the recited function too broadly. According to the Federal Circuit, the '229 patent describes the structure corresponding to the function of defining a functional state of the bus interface unit as a set of flip-flops. The Federal Circuit therefore reversed the district court's construction with respect to the "means for defining" and construed the structural component to include only the set of flip-flops.

The third claim construction issue raised on appeal was the district court's construction of the term "bus interface unit" to mean "a bus interface unit capable of functioning as a bus controller or a remote terminal when connected to a biphase serial bus in a command/response system." The Federal Circuit looked into whether the specification disavowed any embodiment other than one operating in a bus controller/remote terminal environment and concluded that the specification did not. The Federal Circuit considered the stated objectives of the '229 patent and statements made in the Background and Preferred Embodiment Sections of the patent, but did not find any reason to narrowly construe claims 1 and 13 for use only in the bus controller/remote terminal environment.

Accordingly, the Federal Circuit declined to read the bus controller/remote terminal limitation into claim 1 or 13. Instead, the Federal Circuit accorded the term “bus interface unit” its ordinary meaning: a unit for interfacing with a serial data bus.

The Federal Circuit also noted that even though the inventors may have believed that the '229 patent would be used principally in a command/response environment, and that the patent referred repeatedly to the advantages of the invention in that context, these were not found to constitute a limitation on the scope of the invention. Absent a clear disclaimer of particular subject matter, the Federal Circuit found that even if an inventor anticipated that the invention would be used in a particular way does not mean that the scope of the patent is limited to that context.

Claim Preamble Limitation “Reverses” Infringement Finding on Gear Shift Patent

Michael L. Woods

[Judges: Prost (author), Newman, and Dyk]

In *Eaton Corp. v. Rockwell International Corp.*, No. 01-1633 (Fed. Cir. Mar. 27, 2003), the Federal Circuit reversed a jury’s finding of infringement, vacated entry of a permanent injunction, affirmed a judgment of no invalidity, and affirmed a judgment of no inequitable conduct.

Eaton Corporation (“Eaton”) owns U.S. Patent No. 4,850,236 (“the ‘236 patent”) relating to a vehicle transmission shift control system for automatically shifting between a group of gears provided by the transmission. Eaton’s automatic shifting method is aimed at optimizing highway fuel economy.

Eaton sued Rockwell International Corporation and Meritor Automotive Incorporated (collectively “Meritor”) for infringement of the ‘236 patent. To operate Meritor’s transmission, the driver, after determining when to shift, pushes a switch and moves a lever to change gears. Thus, Meritor’s system allows the driver to selectively control which gear the vehicle is in at any time.

In defense, Meritor counterclaimed for a DJ that the ‘236 patent was invalid based on obviousness, lack of enablement, failure to disclose the best mode, derivation, and anticipation. Additionally, Meritor alleged inequitable conduct on the part of the inventor, Eugene Braun, and the attorney who prosecuted the ‘236 patent, for intentionally failing to disclose two other transmission systems to the PTO.

In construing the only independent claim at issue, the district court ruled that the claim’s pream-

ble was not a limitation and, furthermore, that the claim language did not require automatic shifting. In light of this construction, the jury returned a verdict that Meritor literally infringed the claim and the court issued a permanent injunction against Meritor. Additionally, the jury found that the ‘236 patent was not invalid, and the district court found no inequitable conduct.

On appeal, the Federal Circuit reversed the judgment of infringement. In particular, the Court disagreed with the district court’s claim construction, holding that the preamble did, in fact, limit the independent claim. The Federal Circuit explained that the preamble limits the claimed invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. As applied to this case, the Federal Circuit ruled that the independent claim, when properly construed, requires an “automatic mechanical vehicle driveline system” that includes, among other things, “an information processing unit” for processing signals in accordance with a program for causing the engagement of gear ratio combinations. The Federal Circuit noted that according to Meritor’s system, the engagement of gear ratio combinations does not occur automatically as a result of a program running on an “information processing unit.” Meritor’s system, therefore, did not infringe.

Meritor also argued that if the asserted claims are as broad as the district court found, then the claims are anticipated by the other, nondisclosed systems. Because the Federal Circuit narrowed the district court’s claim construction, however, it rejected Meritor’s argument that the narrower claims could be anticipated. Meritor alternatively argued that if the Federal Circuit rejected the district court’s claim construction, Meritor was entitled to a new trial on the invalidity and unenforceability issues. The Federal Circuit disagreed, concluding that the mere fact that a new claim construction has been adopted on appeal is insufficient, in and of itself, to require a new trial.

Meritor also argued that Braun had derived the claimed invention from Dean Anderson of Cummins Engine Company and, as such, was not entitled to the patent under 35 U.S.C. § 102(f). The Federal Circuit, however, agreed with the district court that the balance of the evidence indicated that any disclosure from Anderson to Braun was not in sufficient detail to disclose and enable the complete invention claimed by the ‘236 patent. Thus, the Federal Circuit affirmed the district court’s denial of Meritor’s motion for a new trial on the issue of derivation.

Finally, the Federal Circuit affirmed the district court’s judgment of no inequitable conduct on the part of Braun and his patent attorney. Meritor argued that the evidence showed that Braun and Eaton knew about the other prior art systems and

believed them to be highly material. In affirming the district court's judgment of no inequitable conduct, the Federal Circuit was not persuaded that the district court abused its discretion in finding that Eaton presented credible evidence of good faith during prosecution of the '236 patent.

Prior Art Renders Method for Vibrating Zebra Mussels to Death Unpatentable

George D. Medlock, Jr.

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

In *Mazzari v. Rogan*, No. 02-1269 (Fed. Cir. Mar. 17, 2003), the Federal Circuit affirmed the district court's judgment that Darrel A. Mazzari and Michael T. Sheedy's claims were unpatentable due to anticipation and obviousness.

On April 15, 1992, Mazzari and Sheedy filed U.S. Patent Application No. 07/869,017 ("the '017 application"), claiming an underwater circuit that generated an acoustic wave signal of such magnitude and frequency as to vibrate the shell of a zebra mussel until it broke, thereby killing the animal. The Examiner rejected the claims, and the Board affirmed.

Pursuant to 35 U.S.C. § 145, Mazzari challenged the Board's ruling in the United States District Court for the District of Columbia. The PTO moved for SJ. In response, Mazzari submitted the declaration of Professor Martin E. Boraas, a zoologist, who declared that one of skill in the art would not have combined certain prior art references.

The PTO submitted the declaration of its own expert, who declared that a newly discovered prior art reference anticipated all of the claims and supported the Board's finding that the claims would have been obvious. Based upon this new evidence, as well as the references previously considered by the Board, the district court granted SJ.

On appeal, the Federal Circuit noted that this case raised an important question as to what standard of review a district court under 35 U.S.C. § 145 must apply to Board decisions and what standard the Federal Circuit must apply in reviewing the district court's decision. The Federal Circuit looked to *Dickinson v. Zurko*, 527 U.S. 150 (1999), where the Supreme Court held that the PTO is an agency subject to the Administrative Procedure Act, 5 U.S.C. § 706 (2000) ("APA"). Section 706 of the APA states in part that a reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be unsupported by substantial evidence.

The Federal Circuit determined that a decision by the PTO is reviewed on the administrative record of an agency hearing provided by statute.

Therefore, both the Federal Circuit and the district court must apply the substantial evidence standard of review to findings of fact made by the Board. If additional evidence was presented to the district court, as it was in this case, the district court would make de novo factual findings if the evidence was conflicting. In addition, the Federal Circuit would review the district court's legal conclusions without deference and its de novo factual findings under the "clear error" standard. However, because this case was presented based on SJ, the Federal Circuit reviewed the district court's grant of SJ de novo and construed the facts in the light most favorable to the nonmovant.

The Federal Circuit determined that even construed in the light most favorable to Mazzari, there was no evidence that he performed the method taught in the '017 application. The only support for Mazzari's position was the declaration of Boraas, but he admitted that the device that he had witnessed was not the correct prior art device and that he was not one of ordinary skill in the art. This, taken together with the declaration submitted by the PTO, demonstrated that no issue of material fact existed as to whether one of skill in the art would be motivated to combine the prior art.

The Federal Circuit also considered arguments that the PTO presented before the district court that Mazzari failed to overcome. These additional references both anticipated and rendered obvious the claimed inventions. Mazzari did not dispute the teachings of the additional references nor their combination. Therefore, the Federal Circuit determined that the district court properly concluded that the claimed invention was unpatentable.

Tissue Dissection Patent Invalid

Robert F. Shaffer

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

In *Williams v. General Surgical Innovations, Inc.*, No. 02-1474 (Fed. Cir. Mar. 7, 2003) (nonprecedential decision), the Federal Circuit affirmed a district court's decision granting SJ that the patent was properly held invalid under 35 U.S.C. § 102(b). Plaintiffs had admitted to a commercial use and sale before the critical date; therefore, the sole issue on appeal was simple: whether the asserted claims of U.S. Patent No. 5,655,545 ("the '545 patent") were entitled to the priority date of an earlier-filed pending application, which later issued as U.S.

Patent No. 5,258,026 (“the ‘026 patent”).

The ‘545 patent is directed to improved surgical methods for creating a space or cavity between a patient’s tissues (e.g., between skin and the underlying muscle). In the disclosed method, a surgeon makes an incision into the body and inserts a hollow tissue expander into the incision. Once the expander is in position, fluid is forced into the expander, which causes it to expand and separate the tissues between which it is positioned. The specification of the ‘545 patent also describes in detail the use of the disclosed method for performing endoscopic breast augmentation mammoplasty. The patent states, however, that the description of breast surgery is a “special case” of the use of a hollow, expandable tissue expander for tissue dissection and the formation of a space, cavity, or pocket.

Since the asserted claims of the ‘545 patent relating to dissection all require that the tissue expander be removed upon completion of surgery, General Surgical Innovations, Inc. filed for SJ, asserting that the ‘026 patent did not describe a step of removing the hollow member on completion of surgery, but instead described only a procedure wherein the hollow member is left in place in the body as an implant.

Plaintiffs countered that the ‘545 patent was entitled to the earlier priority date because there is

nothing in the patent that requires the surgeon to leave the tissue expander in the body. The district court disagreed and granted SJ of invalidity.

On appeal, the Federal Circuit also found this argument unpersuasive, concluding that the absence of a requirement to leave the expander in place is not a teaching to remove it. Because the Court found that the ‘026 patent does not, on its face, disclose the removal of the tissue expander, Plaintiff was not entitled to the earlier priority date. And because Plaintiff already admitted to public uses and sales of the claimed invention prior to the ‘545 patent’s critical date, the Court found that SJ of invalidity was indeed proper.

[Michael Jakes of our firm successfully represented Appellee, Origin Med Systems, Inc.]

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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
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