

Last month at

The Federal Circuit



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FORESEEABLE EQUIVALENTS CAN BE FOUND IN THE PRIOR ART

On remand from the Supreme Court, the Federal Circuit affirmed a finding of no infringement under the DOE because the claims were amended for reasons of patentability and the asserted equivalent was found in the prior art and, therefore, was foreseeable at the time of the application. *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, No. 00-1012 (Fed. Cir. June 2, 2003)1

ADVERSE DECISION OF ONE EXAMINER IS MATERIAL INFORMATION FOR APPLICATION WITH SUBSTANTIALLY SIMILAR CLAIMS BEFORE ANOTHER EXAMINER

A contrary decision of another examiner reviewing a substantially similar claim meets the threshold materiality test of information that a reasonable examiner would likely consider important in deciding whether to allow an application to issue as a patent. *Dayco Prods., Inc. v. Total Containment, Inc.*, No. 02-1497 (Fed. Cir. May 23, 2003)2

COURT SETTLES INVENTORSHIP DISPUTE

Inventorship requires conception, which is more than having in mind specific portions of a claimed compound. Conception requires conceiving the compound with all of its component substituents. *Board of Educ. v. American Bioscience, Inc.*, No. 02-1109 (Fed. Cir. June 23, 2003)3

ABSENT SECRECY, STATE LAW AGAINST UNJUST ENRICHMENT CANNOT TRUMP PATENT RIGHTS

Inventor's failure to keep invention secret prevents state-law-based unjust-enrichment claim. *Waner v. Ford Motor Co.*, No. 02-1184 (Fed. Cir. June 4, 2003)4

SALE OF BATTERY-PACK PART EXHAUSTS PATENT RIGHTS

Sale of an unpatented article exhausts the seller's right to control the further sale or use of that article, but only certain circumstances exhaust a seller's patent rights and result in an implied license. *Anton/Bauer, Inc. v. PAG, Ltd.*, No. 02-1487 (Fed. Cir. May 21, 2003)5

NO SAFE HARBOR FOR PRECLINICAL GENERAL BIOMEDICAL RESEARCH

Preclinical research is not exempt from liability for infringement when it identifies drug candidates suitable for future clinical testing but does not supply information for submission to the FDA. *Integra LifeSciences I Ltd. v. Merck KGaA*, No. 02-1052 (Fed. Cir. June 6, 2003)6

COURT REVERSES PART OF CISCO'S SUMMARY JUDGMENT OF NONINFRINGEMENT AGAINST STORAGE TEK

Although district court properly awarded summary judgment of noninfringement on first network communication patent, it erroneously narrowed the scope of claims in a second patent such that summary judgment of noninfringement was improper. *Storage Tech. Corp. v. Cisco Sys., Inc.*, No. 02-1232 (Fed. Cir. May 13, 2003)8

COURT "BREATHES" LIFE BACK INTO ACCUSED VENTILATOR SYSTEM

District court erred in construing several limitations of claims directed to the automatic control of a patient respirator and vacates summary judgment of infringement. *Tehrani v. Hamilton Med., Inc.*, No. 02-1177 (Fed. Cir. June 13, 2003)9

CLAIM TERM "COMPRISING" PERMITS PROCESS STEPS USING TEMPERATURES OUTSIDE OF CLAIMED RANGE

Temperature range of DNA process step does not preclude preliminary steps at temperatures outside the range. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, No. 02-1207 (Fed. Cir. May 7, 2003)9

EDITED BY | VINCE KOVALICK

Foreseeable Equivalents Can Be Found in the Prior Art

[Judges: Mayer (author), Newman, and Lourie (per curiam)]

In *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, No. 00-1012 (Fed. Cir. June 2, 2003), the Federal Circuit, on remand from the Supreme Court, affirmed a judgment of noninfringement under the DOE based on prosecution history estoppel.

The patent-in-suit (U.S. Patent No. 4,677,366) is directed to a “unity power factor power supply” circuitry that levels a varying input voltage into a constant output voltage and steady electrical current source. All but two of the nine originally filed claims were rejected during the prosecution of the application based on prior art. The remaining two claims were rejected as indefinite.

Pioneer Magnetics, Inc. (“Pioneer”) did not dispute the rejection, but instead amended the original claims to include limitations from claims 6 and 7 that were not disclosed in the prior art applied by the PTO. Pioneer explained that it had amended claim 1 to include the substantive limitations of claim 6 with some amendments to overcome the rejection raised for indefiniteness. Pioneer failed to explain, however, why it also amended claim 1 to define the multiplier circuit as a “switching analog” multiplier circuit. After other minor amendments, the patent issued.

While seeking interpretation of the claims, the parties requested the district court to identify what equivalents of the “switching multiplier” limitation, if any, were barred by prosecution history estoppel. In support of its motion, Pioneer offered a declaration by the prosecuting attorney that the reason he added the “switching” limitation to claim 1 was inad-

vertence. The district court had concluded that Micro Linear Corporation’s (“Micro Linear”) nonswitching multiplier was outside the permissible range of equivalents, given Pioneer’s narrowing amendment to add the switching limitation to claim 1. The parties stipulated to a preferred form of judgment for the appeal.

The Federal Circuit had previously affirmed the district court’s decision based on its en banc decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000). However, the Supreme Court returned the decision to the Federal Circuit for reconsideration in light of its *Festo* decision. The parties did not dispute that claim 1 had been narrowed when amended to define the “multiplier” to a “switching analog multiplier.” Thus, the Federal Circuit examined the reasons why the claim was amended, noting that the burden was on Pioneer to establish that the reason for the amendment was not one related to patentability.

Pioneer argued that it had added the “switching” limitation by sheer inadvertence, not for reasons of patentability. The Federal Circuit rejected this argument and Pioneer’s corresponding declaration from its prosecuting attorney. The Court noted that only the public record of the patent prosecution could be a basis for determining the reasons for amendments. Otherwise, the Court explained, the public-notice function of the patent record would be undermined. Moreover, the mere fact that the amendment was voluntary does not mean it did not relate to patentability. Thus, the Court concluded that claim 1 had been amended to overcome the prior art cited by the PTO and to obtain patentability.

Having determined that there was a narrowing amendment for reasons related to patentability, the Federal Circuit next

turned to whether Pioneer could overcome the presumption that it had surrendered the equivalent in question. Based on the Supreme Court's guidance in *Festo* that the presumption could be overcome if the equivalent was unforeseeable at the time of the application, the Court observed that the reference cited during prosecution by the PTO disclosed a nonswitching multiplier circuit. Therefore, the Court concluded, such a circuit was clearly known in the art and would have been foreseeable at the time of the amendment. Because a non-switching multiplier circuit was foreseeable at the time of the amendment, the Federal Circuit ruled that Pioneer was estopped from arguing that a nonswitching multiplier circuit is equivalent to a switching multiplier circuit as claimed. Accordingly, the Court again affirmed the judgment of non-infringement.

Adverse Decision of One Examiner Is Material Information for Application with Substantially Similar Claims Before Another Examiner

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

In *Dayco Products, Inc. v. Total Containment, Inc.*, No. 02-1497 (Fed. Cir. May 23, 2003), the Federal Circuit reversed the district court's grant of SJ of unenforceability and invalidity in favor of Defendant, Total Containment, Inc. ("TCI"), and remanded the case for trial.

Dayco Products, Inc. ("Dayco") sued TCI for infringing certain claims of U.S. Patent Nos. 5,199,752 ("the '752 patent"), 5,297,822 ("the '822 patent"), 5,380,050

("the '050 patent"), 5,129,686 ("the '686 patent"), and 5,486,023 ("the '023 patent") (collectively "the patents-in-suit"), which are directed to flexible hoses and coupling assemblies that connect to each other for use in underground gas-containment systems.

In a prior decision, the district court had granted SJ of noninfringement in favor of TCI. The Federal Circuit, however, reversed-in-part, affirmed-in-part, and remanded that decision.

On remand, the district court again granted SJ in favor of TCI, this time on the ground that the patents-in-suit were unenforceable due to inequitable conduct during prosecution and for invalidity. The district court found inequitable conduct because the attorney that prosecuted the patents-in-suit failed to disclose the existence of a similar copending application and adverse office actions in that application.

The Federal Circuit held that this information was material, finding that the similar copending application could have led to a double-patenting rejection. In addition, for the first time, the Federal Circuit held that a contrary decision of another examiner reviewing a substantially similar claim is material information. The Federal Circuit reasoned that patent disclosures are often very complicated, and different examiners with different technical backgrounds and levels of understanding may often differ. Although examiners are not bound to follow other examiner's interpretations, the Federal Circuit commented that knowledge of a potentially different interpretation was clearly information that is material because an examiner could consider it important when examining an application.

However, the Federal Circuit held that it was not improper for the district court to conclude on SJ that Dayco intentionally

deceived the PTO. The Federal Circuit emphasized that inequitable conduct requires an intent to deceive, which cannot be inferred simply from a decision to withhold a reference. The Court also found that certain facts indicated that Dayco did not have an intent to deceive the PTO and had a plausible explanation as to why the reference was withheld.

As to the district court's SJ of invalidity, the Federal Circuit found that TCI had failed to provide evidence as to why a missing element was necessarily or inherently present in the prior art. In addition, the Federal Circuit found that the district court had improperly grouped the claims and failed to address validity on a claim-by-claim basis. The Federal Circuit emphasized that where claims differ in scope in an aspect material to the analysis, those claims must be addressed individually.

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Court Settles Inventorship Dispute

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

In *Board of Education v. American Bioscience, Inc.*, No. 02-1109 (Fed. Cir. June 23, 2003), the Federal Circuit affirmed the district court's removal of an inventor from U.S. Patent No. 5,780,653 ("the '653 patent") assigned to American BioScience, Inc. ("ABI"), reversed the district court's removal of two inventors from the patent, and vacated the district court's holding that the patent was unenforceable for inequitable conduct.

VivoRx Pharmaceuticals, Inc. ("VivoRx"), ABI's predecessor company, filed the '653 patent application naming Patrick Soon-Shiong, Neil Desai, Chunlin Tao, and Paul Sandford as inventors. The

patent covers three compounds used for anticancer applications, which are analogs of the compound taxotere (generically known as docetaxel).

Prior to joining VivoRx, Tao, a chemist, worked with Professor Robert Holton's research group at Florida State University ("FSU") as a postdoctoral research assistant. Tao, along with Professor Dr. Li-Xi Yang and another doctoral research assistant, Dr. Hossein Nadizadeh, was involved in a collaborative project to develop chemotherapeutic radiosensitizing taxanes ("CRTs") from taxol (generically known as paclitaxel) analogs for anticancer applications. The taxol analogs were made using a semisynthetic process, beginning with a natural product known as baccatin III.

At approximately the same time, Dr. Soon-Shiong, the CEO of VivoRx, and Dr. Neil Desai, VivoRx's senior research scientist, contemplated creating radiosensitizers that they believed would be more potent than taxol by using taxotere instead of taxol as a core structure.

After completing his postdoctoral research at FSU, Tao was hired by Soon-Shiong and Desai to work on the taxotere project at VivoRx in late 1994. Desai assigned to Tao the task of creating chemotherapeutic radiosensitizing taxotere analogs using 10-deacetyl baccatin ("10-DAB"), a compound similar to baccatin III, but having the 10-hydroxy group of taxotere rather than the 10-acetoxy group of baccatin III and taxol. After Tao had made several compounds, the results of his research were forwarded to a patent attorney, who then filed the '653 patent application.

FSU sued Tao in the U.S. District Court for the Northern District of Florida in September 1998, seeking to add Holton, Yang, and Nadizadeh to the '653 patent as inventors and to remove Soon-Shiong,

Desai, and Sandford. FSU also sought a DJ that the patent was unenforceable due to inequitable conduct. Following a bench trial, the district court found, *inter alia*, that (1) Tao had used confidential information that he learned at FSU in synthesizing three compounds that are claimed in the '653 patent; (2) the '653 patent specification disclosed general concepts regarding attaching certain substituents to a taxane to impart radiosensitizing properties that were developed by Yang; and (3) because 10-DAB and baccatin III are essentially interchangeable starting materials, Nadizadeh and Holton obviously knew that 10-DAB could have been used to create one of FSU's taxol analogs. The district court also concluded that Soon-Shiong, Desai, and Sandford did not contribute to the inventions claimed in the '653 patent and removed them as inventors. The district court also added Holton, Yang, and Nadizadeh to the patent as coinventors and concluded that Soon-Shiong and Desai had accordingly engaged in inequitable conduct by not disclosing Tao's former employment at FSU.

On appeal, the Federal Circuit agreed with ABI and ruled that the district court had erred in concluding that Soon-Shiong and Desai were not coinventors, because there was no evidence of record that the idea of making taxol analogs having both a 10-hydroxy group (*i.e.*, taxoteres) and a nitro functional group came from anyone other than Soon-Shiong and Desai.

As to the FSU scientists, the Federal Circuit reversed the district court's decision and ruled that they were not inventors. The Court held that general knowledge regarding the anticipated biological properties of groups of complex chemical compounds is insufficient to confer inventorship status with respect to specifically

claimed compounds. Invention requires conception, and here, the Court stated, there was no evidence that FSU's inventors conceived any of the claimed compounds. The Court explained that having in mind specific portions of a claimed compound is not the same as conceiving the compound with all of its components.

Because the district court's conclusion of inequitable conduct was based on its finding that Soon-Shiong and Desai had failed to disclose to their attorney that Tao formerly worked at FSU, but the Federal Circuit had determined that the FSU scientists were not inventors, the Court vacated the district court's decision on inequitable conduct.

Absent Secrecy, State Law Against Unjust Enrichment Cannot Trump Patent Rights

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

In *Waner v. Ford Motor Co.*, No. 02-1184 (Fed. Cir. June 4, 2003), the Federal Circuit reversed a district court's denial of a JMOL of noninfringement against Ford Motor Company ("Ford") and affirmed a SJ in favor of Ford against Alan Waner's claim of unjust enrichment.

Alan Waner owns U.S. Patent No. 5,613,710 ("the '710 patent"), which discloses a fender liner for dual rear-wheel trucks. In early 1995, Mr. Waner contacted Ford to inquire about their interest in his fender liner, which he originally began to sell in October 1994. Mr. Waner had sold his fender liners to several Ford dealers and set up exhibits at horse shows trying to sell them as well. After Mr. Waner filed his

patent application, he again contacted Ford and met with a Ford engineer for over an hour. The Ford engineer told Waner that he would present Waner's liner at an upcoming meeting.

Later, the Ford engineer prepared a document in which he proposed adding a liner to prevent paint-crack problems on Ford trucks, but he told Waner that the meeting had been postponed. The Ford engineer also told Waner that he could no longer discuss the matter with Waner and referred him to Ford's attorneys. Accordingly, Waner sued Ford for usurpment of an idea/unjust enrichment and infringement of the '710 patent.

A jury found infringement, and the trial court denied Ford's motion for JMOL on noninfringement. The Court had previously granted partial SJ in favor of Ford on Waner's unjust-enrichment claim.

On appeal, the Federal Circuit reviewed the infringement finding and determined that the district court had improperly construed the term "flange" in the claims, concluding that nothing in the specification or prosecution history provided a definition different from the common dictionary definition. The Court also ruled that according to the plain language of the claim, the flange must exist prior to installation of the fender liner. Because Ford's fender liner is a single, planar sheet prior to installation, it does not infringe.

Concerning the unjust-enrichment claim, the Federal Circuit noted that absent secrecy, state law cannot create a collateral set of rights available as an adjunct or expansion to patent rights. Thus, because Waner's invention was in the public domain prior to the issuance of the patent, he cannot be protected by a state-law-based claim for unjust enrichment.

Judge Newman dissented on both rulings. Concerning infringement, she found

the question close and chose to pay deference to the jury's verdict. Concerning unjust enrichment, she concluded that a cause of action for unjust enrichment did not require that the thing taken be maintained as a trade secret. Moreover, she did not see this as a case of simply copying an item in the public domain. Rather, in her view, Ford was clearly enriched at the expense of Waner.

Sale of Battery-Pack Part Exhausts Patent Rights

[Judges: Schall (author), Mayer, and Dyk]

In *Anton/Bauer, Inc. v. PAG, Ltd.*, No. 02-1487 (Fed. Cir. May 21, 2003), the Federal Circuit reversed a grant of a preliminary injunction to Anton/Bauer, Inc. ("*Anton/Bauer*"), finding that the district court had erred when it held that Anton/Bauer had not granted purchasers of certain accused parts an implied license to practice the claimed invention.

Anton/Bauer owns U.S. Patent No. 4,810,204 ("the '204 patent"), which is directed to a battery-pack connection that allows a battery pack to be quickly and efficiently replaced on discharge of the batteries. The claims of the '204 patent each recite a combination of a female plate and a male plate, where the female plate contains a plurality of keyholes or slots and the male plate contains a plurality of projections that correspond to the female keyholes or slots. Each claim further requires a "releasable locking means." Anton/Bauer manufactures and sells the female plates directly to members of the portable-television video-camera industry, who attach them to commercial video cameras and sell them directly to end users as an after-market product. Anton/Bauer also manufactures and sells

battery packs. Defendant, PAG, Ltd. (“PAG”), sells the accused battery packs that can be used in combination with Anton/Bauer’s female plates.

After filing suit, Anton/Bauer moved for a preliminary injunction, which the district court granted.

On appeal, the issue concerning the likelihood of success on the merits turned on the Federal Circuit’s interpretation of the exhaustion doctrine as it applied to Anton/Bauer’s accusations of indirect infringement.

The Federal Circuit stated that sale of an unpatented article exhausts the seller’s right to control the further sale or use of that article, but only certain circumstances exhaust the seller’s patent right and result in an implied license. The Court further confirmed that a patentee grants an implied license to a purchaser when (1) the patentee sells an article that has no noninfringing uses, and (2) the circumstances of the sale plainly indicate that the grant of a patent should be inferred.

The Federal Circuit observed that the district court had based its decision on a finding that the accused battery pack was not a replacement for any component of the mechanical and electrical combination claimed in the ‘204 patent and that the circumstances did not indicate that an implied license had been granted to Anton/Bauer’s customers to practice the patented combination with a male plate from a company other than Anton/Bauer.

The Federal Circuit concluded that sales by Anton/Bauer of the unpatented female plate extinguish Anton/Bauer’s right to control the future use of that plate because the plate can only be used in the patented combination and the combination must be completed by the purchaser. The parties

agreed that there are no noninfringing uses of the female plate sold by Anton/Bauer. Moreover, Anton/Bauer places no express restrictions on the use of the female plates it sells. Nor does it require that manufacturers to whom it sells female plates expressly restrict the grant of a license upon sale of the finished camera product that incorporates the plate. This unrestricted sale of the female plate, the Federal Circuit ruled, grants an implied license to Anton/Bauer’s customers to use the claimed combination.

Accordingly, the Court found no direct infringement to support a claim of either inducement of infringement or contributory infringement. The Court ruled that Anton/Bauer’s customers have an implied license to practice the patented combination during the life of the female plate purchased from Anton/Bauer, regardless of the order that the customer purchased the accused battery pack and the female plate. As such, the Court concluded that Anton/Bauer will not likely succeed on the merits of its claim of inducement or contributory infringement.

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No Safe Harbor for Preclinical General Biomedical Research

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

In *Integra LifeSciences I Ltd. v. Merck KGaA*, No. 02-1052 (Fed. Cir. June 6, 2003), the Federal Circuit upheld a district court’s claim construction and affirmed its ruling that 35 U.S.C. § 271(e) did not immunize Merck KGaA (“Merck”) against liability for patent infringement. The Federal Circuit remanded to the district

court consideration of a jury's \$15,000,000 reasonable royalty reward, after the district court granted Merck's SJ motion asserting invalidity of one of Integra LifeSciences Ltd.'s ("Integra") claims.

Integra owns U.S. Patent Nos. 4,789,734; 4,792,525; 4,879,237; 4,988,621; and 5,965,997 ("the '734, '525, '237, '621, and '997 patents," respectively), which are all related to a short peptide with the amino acid sequence arginine-glycine-aspartate referred to as the "RGD peptide." This peptide mediates the adhesion of cells to their surroundings and plays a role in wound healing and the growth of blood vessels. In the hands of a scientist from the Scripps Institute, for example, it purportedly showed promise for promoting wound healing, attaching prosthetic devices, and treating a plethora of diseases, including cancer and diabetic retinopathy.

Merck entered into an agreement with the Scripps Institute to fund experiments necessary to satisfy the biological bases and FDA regulatory requirements for clinical trials with drug candidates derived from the RGD peptide. Scripps scientists conducted research directed at explaining the mechanism of action of several candidate drugs, determining which could be safely tested in humans, and determining the mode of administering the candidate drugs that would produce the optimum therapeutic effect. This research resulted in the identification of a lead candidate for clinical development.

Integra sued Merck, Scripps, and the scientist in charge of the research that identified the leading drug candidate based on the RGD peptide, asserting that the research infringed its patents. Merck answered that the research was protected by the safe harbor provided by 35 U.S.C. § 271(e)(1), and that Integra's patents were invalid.

The district court granted Merck's SJ motion on claim 2 of the '621 patent, and a jury found Merck liable for infringing the '734, '525, '237, and '997 patents.

The 35 U.S.C. § 271(e)(1) safe harbor encompasses actions "solely for uses reasonably related to the development or submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." The Federal Circuit interpreted 35 U.S.C. § 271(e)(1) by determining whether the safe harbor reaches back down the chain of experimentation to include the identification and development of new drugs that will be subject to FDA approval. It considered that the Scripps-Merck experiments did not supply information to the FDA, but rather identified a lead candidate for testing under the FDA procedures, and concluded that the experiments were not solely for uses reasonably related to FDA clinical tests.

The Federal Circuit reasoned that the central purpose of the exemption is to allow the production of information to the FDA. The term "reasonably" permits some activities that do not directly produce information for the FDA, but, according to the Court, these activities do not include new drug development.

The Federal Circuit placed the context of the safe harbor as facilitating the expedited approval of patented pioneer drugs. It confined the scope of 35 U.S.C. § 271(e)(1) to de minimus encroachment on the rights of the patentee, reasoning that sheltering the Scripps-Merck experiments would effectively vitiate the exclusive rights of patentees owning biotechnology-tool patents, since patented tools facilitate research that identifies candidate drugs.

With respect to claim construction, the Federal Circuit interpreted the term "peptide" as representing two or more amino

acids covalently joined together by peptide bonds. The term “peptide” encompasses peptides of differing structural forms and is not limited to linear peptides, even when the patent does not explicitly refer to a nonlinear, e.g., a cyclic configuration.

With respect to the damages award, the Federal Circuit determined that the record was unclear regarding the date of a hypothetical negotiation between the patentee and the infringer at a time before the infringing activity began. It remanded the issue to the district court to determine when the first infringing activity occurred.

Judge Newman concurred-in-part and dissented-in-part. She concurred that the 35 U.S.C. § 271(e)(1) safe harbor does not reach back down the chain of experimentation to include identification and development of new drugs. Her dissent focused on the question of whether, and to what extent, a patentee’s permission is required to study that which is patented. She argued that the Scripps-Merck experiments were exempt from requiring such permission because the experiments were conducted to understand, improve upon, or modify patented subject matter, and did not include activity associated with the development and commercialization of infringing subject matter.

Court Reverses Part of Cisco’s Summary Judgment of Noninfringement Against Storage Tek

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

In *Storage Technology Corp. v. Cisco Systems, Inc.*, No. 02-1232 (Fed. Cir. May 13, 2003), the Federal Circuit affirmed a SJ of noninfringement with respect to a first

patent, but vacated the judgment with respect to a second patent because of an error in the claim construction.

Storage Technology Corporation (“Storage Tek”) owns U.S. Patent Nos. 5,842,040 (“the ‘040 patent”) and 5,566,170 (“the ‘170 patent”), both relating to data communication networks. Storage Tek sued Cisco Systems, Inc. and Cisco Technology, Inc. (collectively “Cisco”), alleging infringement of both patents. The claims of the ‘040 patent concern a method for caching data in a communication device. The claims of the ‘170 patent recite a protocol data unit processor for forwarding data packets in a communication network.

The Federal Circuit ruled that the district court had improperly relied on certain preamble terms to limit the scope of other terms used in the body of the claim, which was overly restrictive. The Court found that the district court had also improperly relied on the single embodiment in the specification and improperly interpreted statements during the prosecution history to limit the scope of the invention. Finally, the Federal Circuit ruled that the district court had improperly relied on a declaration by Cisco’s expert to support its construction of claim 1.

Having broadened the district court’s claim construction, the Federal Circuit vacated SJ of noninfringement and remanded for further proceedings.

With respect to the ‘170 patent, the Federal Circuit found that a certain phrase in the preamble of the asserted claims was an effective limitation based on applicant’s statements made during the prosecution history and the remaining claim language.

Having confirmed the district court’s claim construction, the Federal Circuit affirmed the district court’s SJ of noninfringement.

Court “Breathes” Life Back into Accused Ventilator System

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

In *Tehrani v. Hamilton Medical, Inc.*, No. 02-1177 (Fed. Cir. June 13, 2003), the Federal Circuit vacated a grant of SJ of infringement to Dr. Fleur Tehrani.

Dr. Tehrani owns U.S. Patent No. 4,986,268 (“the ‘268 patent”), which relates to an apparatus and method for automatically controlling a respirator used for mechanical ventilation of a patient. Dr. Tehrani charged Hamilton Medical, Inc. and Hamilton Medical AG (collectively “Hamilton”) of infringing claims 1 and 16 of the ‘268 patent through the manufacture and sale of its Galileo ventilators. The claims require a device that first processes five data values, including measured levels of carbon dioxide and oxygen levels of the patient and then using these data values to calculate volume and breath frequency.

The Federal Circuit reviewed several claim-construction issues. In particular, the Court concluded that the term “representing” is broad enough to include “symbolizing” or “to stand for,” but elaborated that the term “represents” cannot be interpreted so broadly as to include any case in which two ideas are related in some way. Rather, the first item must be directly related to and stand for, or be a reasonable proxy for, the latter item. Moreover, because the patent uses the terms “indicative of” and “representing” interchangeably, they have the same meaning in the claims.

Claim 1 also includes a “means for processing” limitation. The Federal Circuit noted that “consistent with its precedent,” the structure corresponding to the processing function is the disclosed microprocessor that is programmed to perform the disclosed algorithm. However, the district

court failed to determine the precise algorithm that is part of the recited structure. Nor was the Federal Circuit able to make this determination based on the record. Accordingly, the Court remanded the case to the district court to consider this issue.

Concerning claim 16, in what it called a “close” issue, the Federal Circuit ruled that the claims do not require that all of the method steps recited be performed automatically, thereby excluding manually input data. Concerning infringement, the district court had relied on a manually input “positive end expiratory pressure” (“PEEP”) value selected by an operator of the Galileo ventilators as satisfying the claimed “processing data representing . . . oxygen levels.” The Federal Circuit found that although there is some association between the PEEP level and the level of oxygen in a patient in that the PEEP level may affect the oxygen level, there was no evidence to support the conclusion that the PEEP level “represents” the patient’s oxygen level, as claimed.

Having resolved these claim-construction issues, the Federal Circuit ruled that numerous issues of fact remained concerning whether the accused Galileo product infringes claims 1 and 16. Therefore, the Federal Circuit vacated the district court’s SJ of infringement and remanded for further proceedings on the issue.

Claim Term “Comprising” Permits Process Steps Using Temperatures Outside of Claimed Range

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

The Federal Circuit vacated a SJ finding of noninfringement in *Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, No. 02-1207

(Fed. Cir. May 7, 2003), after finding error with the district court's claim construction.

Invitrogen Corporation ("Invitrogen") filed suit against Biocrest Manufacturing, L.P. and others (collectively "Biocrest") in the U.S. District Court for the Western District of Texas, asserting numerous claims of its U.S. Patent No. 4,981,797 ("the '797 patent"), directed to a method for growing *E. coli* bacteria. According to the district court's claim construction, the claimed method required a growing step that was limited to a specified temperature range and excluded growing in temperatures outside that range. Applying that construction, the district court granted SJ of no infringement, because the accused method included a preliminary growing step under temperature conditions outside the claimed range. The Federal Circuit vacated that ruling, holding that the claim term "comprising" left open the possibility of growing steps outside the claimed range and that the district court failed to read the claim in the context of the relevant scientific field.

E. coli is a bacteria commonly used in DNA technology to produce beneficial proteins. The '797 patent claims a process for making *E. coli* cells with an enhanced capacity to accept foreign DNA with increased competence (the cell's capacity for accepting foreign DNA). In relevant part, claim 1 of the '797 patent claims "a process for producing transformable *E. coli* cells of improved competence by a process comprising . . . growing *E. coli* cells in a growth-conducive medium at a temperature of 18°C to 32°C . . ." In rejecting the original application claim directed to a temperature range of "less than 37°C," the Examiner stated that the range of 18°C to 32°C was essential to the invention. In response, the applicant amended the claim to include that range and also noted that

the invention avoids undesirable growth effects at 37°C. Based on this prosecution history, the district court concluded that the applicant disclaimed all growth outside the range of 18°C to 32°C.

The Federal Circuit disagreed, explaining that the transition "comprising" indicates that the claim is open-ended and allows for additional steps, including steps that produce *E. coli* growth before the recited steps. Thus, the claim itself does not preclude other growth.

Additionally, to illuminate the claims' meaning and reach, the Court considered the context of the scientific field embodied in the patent specification. For example, the specification discussed the preparation of master seeds (*E. coli* cells in long-term frozen storage that are processed into primary seeds that are used in the claimed method) by growing the *E. coli* cells at 37°C.

With respect to the prosecution history relied upon by the district court, the Federal Circuit concluded that during prosecution, the applicant simply specified the growing requirements for achieving competence in the cells. The Federal Circuit also noted that during prosecution, the applicant did not address growth at 37°C that occurs before initiation of the claimed method. Accordingly, the Federal Circuit held that the claim scope does not preclude preparatory steps in advance of the claimed growing step at a temperature outside the claimed range of 18°C to 32°C.

Invitrogen also disputed the district court's claim construction that the preamble term "improved competence" limited the claims, arguing that the preamble term should not be limiting because it simply stated an intended advantage. Biocrest countered that while the district court had correctly concluded that the preamble

term was a claim limitation, it should have further construed the term to require at least a ten-fold increase in competence. The Federal Circuit upheld the district court's construction, agreeing that the preamble term acted as a limitation, because, during prosecution, the applicant had clearly relied on the preamble to distinguish the invention from the prior art. Specifically, in overcoming a rejection of claims that did not require increased competency, the applicant amended the preamble to recite "improved competence" and repeatedly argued that this feature distinguished the invention from the prior art. The Federal Circuit further found that the district court had correctly consulted the overall context of the claim language to determine the limiting effect of the claim language and test data in the prosecution history and patent specification showing

varying amounts of increased competence. For these reasons, and because neither the claim language, specification, nor prosecution history contained any specific numerical limitation, the Federal Circuit upheld the district court's construction of the preamble term "increased competence."

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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