# Last month at | The Federal Circuit



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

## Federal Circuit Balances Nuances of Claim Construction with Requirements of 35 U.S.C. § 112

*Maria T. Bautista*

**[Judges: Michel (author), Schall, and Clevenger (dissenting)]**

In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, No. 01-1191 (Fed. Cir. Jan. 6, 2003), the Federal Circuit affirmed-in-part and vacated-in-part the district court's rulings and remanded for further proceedings.

Amgen, Inc.'s ("Amgen") five patents-in-suit relate to a non-naturally occurring protein, erythropoietin ("EPO"), for treating patients who lack normal levels of naturally occurring EPO. Amgen pioneered a commercial process for producing EPO by transfecting exogenous (i.e., foreign) DNA into Chinese hamster ovary cells. As a result, the cells expressed human recombinant EPO in significant amounts.



Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc. (collectively "TKT") later developed another method to produce EPO by using an endogenous (i.e., naturally occurring) EPO gene in human cells. TKT transfected a viral promoter and other DNA to alter the endogenous EPO gene, thereby causing the human cells to produce EPO in greater abundance.

Amgen's asserted claims are not limited to the use of exogenous DNA or nonhuman cells. However, TKT alleged that Amgen's specification limited the invention, hence the claims, to the use of exogenous DNA, pointing, e.g., to a description of EPO as being "uniquely characterized . . . [as] the product of prokaryotic or eukaryotic host expression . . . of exogenous DNA sequences." The Federal Circuit disagreed that the claims should be so limited. Relying in part on the doctrine of claim differentiation, the Court found that a nonasserted claim reciting "exogenous DNA" provided a rebuttable presumption that the asserted claims have a different scope. Additionally, the Court did not apply much weight to the Examiner's remarks commenting that the application taught only cells transformed with exogenous DNA, because the Examiner eventually allowed broader claims.

The Federal Circuit also upheld the district court's construction that "non-naturally occurring," "vertebrate cells," and "mammalian cells" should be given their ordinary and customary meaning to encompass the use of human cells. Amgen's specification disclosed the use of human cells in culture and the Court found no record of Amgen's clear disavowal of human cells.

The Federal Circuit affirmed the district court's holding that Amgen's failure to describe the use of endogenous DNA in its specification did not invalidate the claims for lack of written description. The Federal Circuit agreed with the district court that the claims at issue were directed to compositions, and thus the written description inquiry need not address how the product was made or any future developments of the process for making EPO.

The Court also found that Amgen's specification sufficiently described all vertebrate and mammalian cells and did not expressly exclude the use of exogenous human EPO DNA in human cells or endogenous DNA. Even though the specification described only two species of vertebrate or mammalian cells, neither of which were human cells, the Court found that one of ordinary skill in the art could recognize the identity of the members of the genus, including human cells. Moreover, the Court found that vertebrate or mammalian cells did not relate to new or unknown biological species that could be miscomprehended by one of ordinary skill in the art, unlike the technology in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). There, the claims required a precise definition of the DNA sequence itself. The Court found this distinct from Amgen's claims, which related to the EPO-producing cell and not to the DNA itself.

TKT cited *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998), to support its position that Amgen's failure to explicitly claim the use of exogenous DNA omitted an "essential" feature of the invention. The *Gentry* court had invalidated the claims for lack of written description because the patent did not adequately describe a sectional sofa having reclining controls in a location other than on the console. The Court found that Amgen's allegedly limiting statements in the specification did not rise to the level of the *Gentry* specification, which expressly limited the location of the controls to the only possible location. In contrast, Amgen's invention was not about sequence location, but rather, it was about the production of human EPO using those sequences, according to the Court.

The Federal Circuit found certain composition claims enabled even though the claims covered compositions derived from TKT's endogenous DNA method developed after Amgen's application was filed. Again, the Court determined that the method for making the composition was immaterial to the enablement inquiry for a composition claim, and, thus, Amgen did not need to describe later-developed methods for preparing the compositions. Because the specification needs only to teach one mode of making and using a claimed composition—a requirement Amgen satisfied—the Court

stated that Amgen's failure to describe endogenous activation was legally irrelevant.

Amgen was also entitled to claims covering all "vertebrate cells" able to produce certain levels of human EPO, even though Amgen only described one technique for making the claimed EPO-producing cell. Although disclosing only one or two species may not enable a broad genus, the Court found that Amgen easily bridged any gaps between the disclosure and the claim scope, because expert testimony and postfiling publications established that the skilled artisan could have readily used various vertebrate and mammalian cells to produce human EPO and could have determined whether certain promoter and vertebrate cells would work.

With regard to validity based on prior art, the Court concluded that prior art patents are presumed enabled for both claimed and unclaimed subject matter. The Court noted that the PTO can presume a cited prior art patent is operable, thus shifting the burden to the applicant to rebut this presumption. Similarly, the Court reasoned, district courts should be entitled to presume enablement for the entire patent disclosure. A patentee can overcome this presumption by providing persuasive evidence of nonenablement. The Federal Circuit then found that the district court had improperly placed the burden of rebuttal on TKT, although this was harmless error. The Court, nonetheless, remanded the novelty issue to the district court in light of a new claim construction.

Amgen's failure to identify a standard test for determining whether "glycosylation . . . differs from that of human urinary erythropoietin" rendered those claims invalid for indefiniteness under § 112, second paragraph. The specification describes three different methods for measuring glycosylation, but the district court found the claims not limited to those methods. Amgen contended that one of ordinary skill in the art could identify a standard test based on its specification. Evidence, however, showed that the urinary EPO itself, which was the standard for comparison, produced variable glycosylation patterns. For example, experiments showed different glycosylations for two urinary EPO samples prepared from the same batch of starting materials. In light of the variability of the standard and Amgen's failure to teach a standard test for glycosylation, the Court found the claim indefinite as no narrowing construction could be properly adopted.

## Herbicide-Resistant Plant Patent Fails to Resist Nonenablement and Noninfringement Challenges

*Timothy B. Donaldson*

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

In *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, No. 02-1011 (Fed. Cir. Jan. 13, 2003), the Federal Circuit affirmed the district court's ruling that certain claims of Plant Genetic Systems, N.V.'s ("PGS") U.S. Patent No. 5,561,236 ("the '236 patent") were invalid for lack of enablement and that the remaining asserted claims of the '236 patent were not infringed.

The '236 patent claims a priority date of March 11, 1987, and is directed to transgenic plant cells, plants, and seeds that contain an herbicide-resistant gene. DeKalb Genetics Corporation ("DeKalb") makes and sells transgenic corn seeds that contain an herbicide-resistant gene. PGS sued DeKalb for infringement the day the '236 patent issued.



The '236 patent describes genetically engineered plant cells that express a gene encoding a protein that prevents herbicides, such as bialaphos or glufosinate, from blocking the activity of glutamine synthetase. As a result, plants containing these genetically modified cells can grow in the presence of these glutamine-synthetase inhibitors, while other surrounding plants or weeds die. Claims 1-5 and 10-11 ("the cell claims") are directed to cell, tissue, and culture claims. The cell claims depend from claim 1, which is directed to a plant cell comprising a heterologous DNA encoding a protein that inactivates a glutamine-synthetase inhibitor in the plant cell. Claims 8-9 and 12-15 ("the plant and seed claims") are directed to plants and seeds consisting of the cells of claim 1, where the plant or seed is "susceptible to infection and transformation by Agrobacterium and capable of regeneration thereafter."

A key issue in this case was the scope of the terms "plant" or "plant cell" in the claims. Flowering plants can be broadly categorized as either monocotyledons ("monocots") or dicotyledons ("dicots"), based on whether the initial seedling develops one leaf (monocot) or two leaves (dicot). In the '236 patent, all the working examples involve dicots. DeKalb's transgenic corn, on the other hand, is a monocot.

The district court concluded that the cell claims were invalid for lack of enablement because it

would have required undue experimentation as of March 11, 1987, to carry out stable gene transformation in monocots. On appeal, PGS argued that the district court's invalidity decision should be reversed because the district court (1) failed to make any findings regarding the pioneering nature of the claimed invention; (2) improperly shifted the burden of proof by requiring the patentee to establish enablement; (3) failed to consider all relevant evidence; and (4) improperly relied on posteffective filing date work in evaluating enablement. The Federal Circuit considered each of these arguments and found none of them persuasive.

First, the Federal Circuit found no precedent to support PGS's argument that a "pioneering" patent is entitled to a lower standard of enablement. Accordingly, the district court did not err by not making any findings regarding the "pioneering" status of the '236 patent.



Next, PGS argued that the district court had improperly shifted the burden of proof to PGS by using *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993) as a starting point for the state of the art in 1985 regarding Agrobacterium-mediated transformation of corn and then looking for evidence between 1985 and 1987 to alter the *Goodman* conclusion that reliable transformation techniques for monocots did not exist in 1985. The Federal Circuit rejected this argument, finding that the district court did not exclude any evidence that could rebut the findings of *Goodman* and that the district court's search for evidence of enablement between 1985 and 1987 did not shift the burden to PGS, but rather indicated the strength of the nonenablement evidence.

The Federal Circuit also rejected PGS's argument that the district court did not consider certain documents cited by PGS, observing that the district court's failure to cite every piece of evidence in its opinion does not, by itself, establish that the evidence was not considered. Rather, a presumption exists that the fact finder reviewed all the presented evidence unless explicitly expressed otherwise.

Finally, the Federal Circuit found that the district court had properly relied on post-1987 work as evidence of the state of the art in 1987. The Federal Circuit agreed with the district court that the reporting of a first successful monocot transformation after 1987 suggests failure or difficulty in or before 1987.

PGS also appealed the district court's claim construction for the plant and seed claims and sought reversal of the district court's noninfringement decision. Based on the specification and prosecution history of the '236 patent, the district court construed the limitation "susceptible to infection and transformation by Agrobacterium and capable of regeneration" as excluding monocots. In particular, during prosecution of the '236 patent, the Examiner rejected the plant and seed claims as nonenabled for monocots, including corn. PGS overcame the rejection by adding the limitation at issue. Accordingly, the district court held that DeKalb's monocot corn products did not infringe the plant and seed claims of the '236 patent.

On appeal, PGS argued that the district court had ignored the plain meaning of the claim language, which covers any plant, monocot, or dicot. The Federal Circuit, however, disagreed. Relying on the prosecution history alone, it held that the district court did not err in its claim construction. Finally, the Federal Circuit rejected PGS's argument that the district court had erred in considering extrinsic evidence to construe the plant and seed claims. Here, the district court properly consulted the intrinsic evidence and then considered extrinsic evidence to ensure that its claim interpretation was not inconsistent with the understanding in the relevant technical field.

## Federal Copyright Law Does Not Preempt Software Shrink-Wrap License

*Donald D. Min*

**[Judges: Rader (author), Clevenger, and Dyk (dissenting)]**

In *Bowers v. Baystate Technologies, Inc.*, No. 01-1108 (Fed. Cir. Jan. 29, 2003), the Federal Circuit issued a revised opinion vacating its original opinion entered August 20, 2002, *Bowers v. Baystate Technologies, Inc.,* 302 F.3d 1334 (Fed. Cir. 2002). In the revised opinion, the Federal Circuit further clarified its reasoning as to why Harold L. Bowers's shrink-wrap license agreement ("the Agreement") was not preempted by the federal Copyright Act. In addition, the Federal Circuit again affirmed the jury's verdict that Baystate Technologies, Inc. ("Baystate") had breached the Agreement and again reversed the verdict that Baystate had infringed Bowers's U.S. Patent No. 4,993,514 ("the '514 patent").

Bowers sold a bundle of computer-aided design ("CAD") programs called the Designer's Toolkit, and the Agreement prohibited any reverse engineering of the programs in the Designer's Toolkit. In addition, the Designer's Toolkit included a user-template feature that was claimed by the

'514 patent. Baystate obtained copies of the Designer's Toolkit, reverse-engineered many of its features, and introduced its own product called Draft-Pak version 3.

In May 1991, Baystate sued Bowers for a DJ that, among other things, its products did not infringe the '514 patent. Bowers counterclaimed for copyright infringement, breach of contract, and patent infringement. A jury found for Bowers and awarded damages for each of the counterclaims. The district court, however, set aside the copyright damages as duplicative of the contract damages. Baystate appealed, arguing that the Copyright Act preempted Bowers's state-law claim for breach of the Agreement. Bowers also appealed, arguing that the copyright damages should not have been set aside.

In its first opinion entered August 20, 2002, the Federal Circuit held that, under First Circuit law, the Copyright Act did not preempt the state-law breach of contract claim. The Court reasoned that the First Circuit would hold that the Copyright Act does not preempt contractual restraints on copyrighted articles because a state-law contract claim requires proof of extra qualitative elements, such as mutual assent and consideration, that are beyond a federal-copyright claim. Therefore, the Court concluded that the First Circuit would have found no preemption of the Agreement.

In its revised opinion entered January 29, 2003, the Court further clarified that it left unaltered the conclusions reached in *Atari Games Corp. v. Nintendo of America, Inc.*, 975 F.2d 832 (Fed. Cir. 1992), where it held that the Copyright Act defined the circumstances in which reverse engineering of a computer program was considered fair use. The Court noted that, in the present case, its application of First Circuit law was for determining whether the state-law contract claim was distinguishable from the federal-copyright claim and had not changed the federal-law definition of fair use. Therefore, the Court concluded that the findings of *Atari* were not altered by the present decision.

In addition, the Federal Circuit acknowledged that the Fifth Circuit had held that the federal Copyright Act preempted a state law prohibiting all copying of a computer program. The Federal Circuit found, however, that the First Circuit would not extend the Fifth Circuit's ruling to preempt a contract between private parties. The Federal Circuit found that the First Circuit would hold that private parties to a contract are allowed to waive their rights to reverse-engineer a product under exemptions of the Copyright Act. Therefore, the Federal Circuit concluded that the Agreement was not preempted under First Circuit law.

Having settled the preemption issue, the Federal Circuit found that substantial evidence supported the jury's verdict of breach of contract. Among other things, the Court noted that the record showed the extensive similarities between the Designer's Toolkit and Baystate's product, including the same unusual, idiosyncratic design choices and inadvertent design flaws. Therefore, the Court agreed that the evidence showed Baystate had reverse-engineered the Designer's Toolkit in violation of the Agreement.

Concerning patent infringement, the Court construed the claims differently than did the district court and concluded, given that construction, that no reasonable jury could have found infringement. The Court also found that the district court had not abused its discretion in omitting the copyright damages since both the contract and copyright damages arose from the same copying by Baystate.

Judge Dyk concurred-in-part, but dissented with the majority insofar as it holds that the contract claim is not preempted by federal law. He concluded, based on the petition for rehearing and opposition, that a state is not free to eliminate the fair-use defense provided under federal copyright law. He argued that, unlike a negotiated contract, shrink-wrap licenses allow a copyright holder to unilaterally eliminate the fair-use defense.



## Patentee Permitted to Prove Lost Profits

*Gordon P. Klancnik*

**[Judges: Rader (author), Schall, and Bryson]**

In *Micro Chemical, Inc. v. Lextron, Inc.,* No. 02-1121 (Fed. Cir. Jan. 27, 2003), the Federal Circuit reversed the district court's judgment that lost profits were not available, vacated the reasonable royalty award, and denied the patentee's request for a new judge on remand.

Micro Chemical, Inc. ("Micro Chemical") sued Lextron, Inc. ("Lextron") over fourteen years ago for infringing U.S. Patent No. 4,733,971, which relates to systems using weight to measure and dispense microingredients, such as medicines and nutritional supplements, added to livestock and poultry feed. Both parties provide these systems to feedlots for free, expecting that each feedlot will, in turn, purchase its microingredients from whichever company provided the equipment. Two prior appeals to the Federal Circuit discussed validity and infringement—this appeal discussed damages. In particular, the lower court determined that Micro Chemical was not entitled to lost profits, because it

could not prove "but for" causation using either the *Panduit* test or the two-market supplier test.

More specifically, the district court ruled that Micro Chemical could not prove two of the four *Panduit* factors—the absence of noninfringing substitutes and demand for the patented product. With respect to the alleged absence of noninfringing substitutes, the Court explained that a substitute, even though not on sale during the infringement, may affect the damages calculation only if the material and know-how of the substitute were readily available. In this case, the substitute, which took Lextron over thirteen hundred hours to design and test, was not readily available. Not only did it require specially manufactured parts not maintained in inventory, but Lextron also hired consultants to ensure its efficacy.

With respect to the lack of demand, the Court clarified that demand existed for Micro Chemical's machines, even though they were provided gratis. Indeed, the machines had commercial advantages over other microingredient dispensers, and each company profited, at least indirectly, from their placement with feedlots.



Before explaining Micro Chemical's entitlement to use the two-market supplier test, the Federal Circuit clarified that this test essentially collapses two of the *Panduit* factors into an inquiry into the relevant market and the number of suppliers. The Federal Circuit concluded that the district court had erred in not defining the relevant market as the market for machines that dispense microingredients by weight. Because the Court ruled that Micro Chemical would be allowed to prove lost profits on remand, it also vacated the reasonable royalty award.

Lastly, the Federal Circuit denied Micro Chemical's motion for a different judge on remand. Using Tenth Circuit law, the Court found neither that the judge held a personal bias nor that reassignment would be in the best interests of justice. The mere fact that the Federal Circuit had twice reversed portions of the district court's previous rulings was insufficient to show any favoritism toward Lextron or antagonism toward Micro Chemical.

## Limited Disclosure in Patent Specification Limits Scope of Claims

*Michael A. Holtman*

**[Judges: Newman (author), Friedman, and Rader (concurring)]**

In *Biogen, Inc. v. Berlex Laboratories, Inc.*, No. 01-1058 (Fed. Cir. Jan. 31, 2003), the Federal Circuit affirmed the district court's claim construction for Berlex Laboratories, Inc.'s ("Berlex") U.S. Patent Nos. 5,376,567 ("the '567 patent") and 5,795,779 ("the '779 patent"), affirmed the SJ of no literal infringement of the '567 patent and noninfringement of the '779 patent, and vacated the SJ of no infringement under the DOE for the '567 patent.

The '567 patent and '779 patent, a continuation of the '567 patent, relate to the production of human interferon in Chinese hamster ovary ("CHO") cells. At issue was whether Berlex's patents claim both "linked" and "unlinked" cotransformation of CHO cells. Linked cotransformation describes a process of inserting foreign DNA into a cell using a single vector containing all the desired genes, such as the human-interferon gene and a marker gene. Unlinked cotransformation, on the other hand, describes a transformation technique where the desired genes reside on separate vectors. Biogen, Inc. ("Biogen") uses an unlinked cotransformation approach to insert the human-interferon gene and a marker gene into CHO cells.

The district court had determined that the '567 patent specification discusses a single construct method for inserting foreign DNA into CHO cells, that this procedure limits the scope of all claims, and that the prosecution history and testimony by expert witnesses supported this narrower scope of the '567 patent claims. On appeal, Berlex pointed to language in the specification and prosecution history that indicates that the '567 patent claims cover both (1) the use of CHO cells to produce high levels of human interferon generally, and (2) the use of a single construct carrying the human-interferon gene and a selectable marker. Berlex argued that linked cotransformation is only a preferred embodiment and, thus, not limiting on the scope of the broader claims. Finally, Berlex noted that the '567 patent application was filed after claims specific to a single DNA construct had been allowed in the parent application, U.S. Patent No. 4,966,843 ("the '843 patent"), and that the '567 patent claims were intended to be of different scope.

Biogen responded that Berlex's asserted breadth of the '567 patent claims is not supported by the specification and would render the '567 patent invalid for lack of an adequate written description. Biogen further responded that, but for a few general statements, the entire specification of the '567 patent is directed solely to the invention, whereby a single construct comprising the human-interferon gene and a marker gene is used to insert the DNA into CHO cells.

The Federal Circuit agreed with Biogen and affirmed the district court's ruling that the '567 patent specification defines the invention as the use of a single DNA construct to introduce the linked human-interferon gene and selectable-marker gene into CHO cells. The Federal Circuit found that the

prosecution record shows that the Examiner also viewed the invention of the '567 patent application as the use of a single DNA construct. In doing so, the Federal Circuit noted the Examiner's comments made during an obviousness-type double-patenting rejection and in his Reasons for Allowance both indicate to the interested public that the PTO viewed the use of a single DNA construct with linked genes as the only supportable scope of the claims.

The Federal Circuit further addressed Berlex's statement that the district court had improperly relied on arguments made in the prosecution of the parent '843 patent to limit the '567 patent claims. The Court agreed that while such statements should not automatically apply to limit different claims in a separate application, they can do so in some circumstances. The Court commented that the statement by the applicant during the '567 patent prosecution that the '567 patent claims "fall within the scope of subject matter already allowable over the prior art" weighs heavily against the applicant's proposed broader construction in the later application. Additionally, the Court noted that the applicant's comments during prosecution cannot enlarge the content of the '567 patent specification.

With respect to infringement of the '567 patent, the Federal Circuit affirmed the SJ of no literal infringement, but reversed the SJ of noninfringement under the DOE, based on prosecution-history estoppel. The Federal Circuit noted that in prosecuting a related application, the applicant is not barred from raising new arguments or correcting past errors. Thus, the district court had erred when it summarily concluded that Berlex was estopped from asserting that multiple DNA constructs for unlinked cotransformation infringe by equivalence based on the fact that the applicant has disclaimed such use in the parent '843 patent. The Federal Circuit remanded this portion of the case to determine the facts of infringement by equivalency.

The district court next addressed Berlex's '779 patent, which claims a CHO cell-culture composition wherein the human interferon is secreted at a concentration range of 150,000-600,000 IU/ml of medium. The district court determined that the claimed concentration of 150,000-600,000 IU/ml must represent interferon concentrations obtained at the end of the production process. In so holding, it found that even though Biogen's CHO culture composition secreted interferon within that range, it did so only as the cell composition continued to a final interferon concentration of 1,200,000 IU/ml. In other words, the district court held that traversing the range set forth in the '779 patent claims was not sufficient for infringement when the final concentration fell outside of that range.

The Federal Circuit agreed but also noted that during the prosecution of the '779 patent, the applicant told the Examiner that the activity limits of 150,000-600,000 IU/ml were included in the claims only to expedite prosecution. The Court concluded that claims deliberately limited to expedite prosecution could not later regain a broader scope for infringement purposes.

## ANDA Submission for Unpatented Use of Drug Covered by Patent Does Not Infringe

*Jennifer Gray Beckman*

**[Judges: Lourie (author), Michel, and Plager]**

In *Warner-Lambert Co. v. Apotex Corp.,* No. 02-1073 (Fed. Cir. Jan. 16, 2003), the Federal Circuit affirmed the district court's SJ of noninfringement on the ground that submission of an Abbreviated New Drug Application ("ANDA") for an FDA-approved, off-patent use of a drug does not constitute a § 271(e)(2)(A) act of infringement when a different claimed use is still under patent protection.



Warner-Lambert Company ("Warner-Lambert") is the assignee of several patents regarding the drug gabapentin, sold under the trade name Neurontin®. The first patent, expired U.S. Patent No. 4,024,175, claimed the actual compound. The second patent, expired U.S. Patent No. 4,087,544, claimed a method of treating certain cranial dysfunctions, such as epilepsy, with gabapentin. The third patent, U.S. Patent No. 5,084,479 ("the '479 patent"), claims the use of gabapentin for the treatment of neurodegenerative diseases such as stroke, Alzheimer's disease, Huntington's disease, and Parkinson's disease.

Warner-Lambert obtained FDA approval for the use of gabapentin to treat seizures in adults with epilepsy in 1993. The FDA has not approved gabapentin for any other uses, notably not for use in treatment of neurodegenerative disorders.

Apotex Corporation ("Apotex") filed an ANDA in 1998, seeking FDA approval to market a generic form of gabapentin for use as a treatment for epilepsy upon the expiration of Warner-Lambert's epilepsy method patent in early 2000. Included in the ANDA was a certification that its proposed manufacture, sale, and use of gabapentin would not infringe the '479 patent, declaring that its labeling would not include any indication for use in treatment of neurodegenerative diseases.

Warner-Lambert filed suit, alleging that Apotex's submission of its ANDA was an act of infringement of the '479 patent. Despite the lack of FDA approval for the use of gabapentin for neu-

rodegenerative diseases, they argued, patients and doctors will use and prescribe the Apotex generic for all the purposes which Neurotin® is customarily used. The district court granted Apotex's motion for SJ, and Warner-Lambert appealed.

The Federal Circuit stated that this case presented an issue of first impression: whether it is an act of infringement under 35 U.S.C. § 271(e)(2)(A) to submit an ANDA seeking approval for an FDA-approved use of a drug if any other use of that drug is claimed in a patent.

Warner-Lambert argued that the statutory definition of "act of infringement" extends to cover ANDAs filed for a drug having any claimed use in a patent. The Court rejected Warner-Lambert's reading of the statute, concluding that it eviscerated an important part of the statutory provision by conflating the first and second clauses of § 271(e)(2)(A) in its quotation. Specifically, the phrase "before the expiration of such patent" cannot be read apart from the phrase "if the purpose of such submission is to obtain approval under such act." The Court noted that the statute may be somewhat unclear, but nevertheless found no merit in Warner-Lambert's interpretation. "It is abundantly clear that the statute does not make the filing of an ANDA prior to patent expiration an act of infringement unless the ANDA seeks approval to make, use, or sell the drug prior to expiration of a patent *that would otherwise be infringed* by such manufacture, use or sale, *apart from* the provisions of § 271(e)(2)." *Warner-Lambert*, slip op. at 9-10 (emphasis in original).



The Federal Circuit also looked to the legislative history to support its reading of § 271(e)(2)(A). If Warner-Lambert's interpretation were correct, and an ANDA filing constituted an act of infringement for any use of the drug that was still covered by a patent, a New Drug Application ("NDA") holder would be able to maintain exclusivity in the market by regularly filing new applications claiming methods of use not covered by its NDA, the Court concluded. This would frustrate one of the stated purposes of the Act: allowing market entry by generic manufacturers. The Court pointed at language in the House Report demonstrating that Congress recognized that a single drug could have more than one indication, and yet that the ANDA applicant could seek approval for less than all of those indications.

The Federal Circuit also considered the question of whether Warner-Lambert had demonstrated the existence of a genuine issue of material fact with respect to inducement to infringe under § 271(b). Warner-Lambert argued that the district court had erred in requiring proof of Apotex's knowledge that physicians were prescribing gabapentin for treatment of neurodegeneration, contending that the correct standard is "should have known." The Court responded that specific intent and action to induce infringement must be proven. In the absence of any evidence that Apotex has or will promote or encourage doctors to infringe the neurodegenerative method patent, the Court found no genuine issue of material fact. The Court observed that especially where a product has substantial noninfringing uses, intent to induce cannot be inferred, even when the defendant has actual knowledge that some users of its products may be infringing the patent.

## Notebook Entries Fail to Show Possession of DNA Construct

*L. Scott Burwell*

**[Judges: Lourie (author), Friedman, and Prost]**

In *Singh v. Brake*, No. 01-1621 (Fed. Cir. Jan. 29, 2003), the Federal Circuit affirmed the Board's decision awarding judgment in an interference to Anthony Brake. The Board had held that Brake's parent application adequately described and enabled the invention of the count, thereby entitling Brake to the filing date of that application. The Board had further held that Arjun Singh had not met his burden of proving conception prior to the filing date of Brake's parent application and that Singh also had not met his burden of demonstrating diligence between conception and reduction to practice. The Federal Circuit affirmed these rulings.

The count at issue in the interference was directed to a DNA construct for use in expressing and secreting foreign proteins in yeast. Brake's parent application disclosing the subject matter of the count was filed on January 12, 1983, and the patent issuing from a continuation-in-part of that application was assigned to Chiron Corporation. Singh, whose application was assigned to Genentech, Inc., alleged that he conceived the subject matter of the count in late 1982.

Singh's attempts to develop the DNA construct of the count began in October 1982, when he was informed that the protein he was trying to express from that construct contained eight additional amino acids not present in the natural protein. Singh then devised a plan to redesign the construct to remove the nucleotides encoding the extra amino acids and testified that in November 1982 he had ordered a nucleotide sequence for use in an experiment designed to delete the extra amino acids. That order was canceled on the same day and, a week later, a different nucleotide sequence was ordered for the deletion experiment.

Singh argued on appeal that the Board had failed to consider the totality of the corroborative evidence that he had offered to establish his 1982 conception, namely, three laboratory-notebook entries that he asserted should be read together. The Federal Circuit rejected that argument, concluding that the November notebook entry recording the first order of the nucleotide sequence for use in the deletion experiment merely expressed the problem to be solved, but did not provide a solution. The Court also noted that the nature of the sequence ordered in November cast doubt on the accuracy of Singh's testimony that he had ordered that sequence for use in a deletion experiment.

The Federal Circuit also agreed with the Board that nothing in Singh's notebook corroborated his testimony that the three laboratory-notebook entries were meant to be read together. Even assuming that they were, the Federal Circuit ruled that the totality of the evidence was insufficient to prove by a preponderance of the evidence that Singh had a definite and permanent idea of an operative method for making the DNA construct prior to Brake's filing date. The Court agreed with the Board that the notebook entries did not provide any protocol or outline of the deletion experiment, and that the entries at best stated a goal that Singh hoped to achieve. The Federal Circuit also concluded that Singh had failed to prove reasonable diligence toward reduction to practice by a preponderance of the evidence, as the laboratory-notebook pages relied on by Singh were unexplained as to content and relevance as well as being uncorroborated.

Singh also appealed the Board's determination that Brake was entitled to the January 12, 1983, filing date of his parent application. Singh asserted that Brake did not provide an adequate written description of the invention of the count in that parent application because the application disclosed a large genus of over 9000 species, whereas the count was directed to only two species, and that the parent application did not provide adequate direction to lead a person of ordinary skill in the art to the subgenus of the count. The Federal Circuit rejected that argument, disagreeing with Singh's calculation of the total number of species disclosed in the priority application and concluding that the parent application disclosed at most seventeen species, only two of which were meaningful embodiments. The Federal Circuit also noted that the disclosure of one of the original claims of the parent application provided a clear blaze mark providing *in ipsis verbis* support for the subject matter of the count.

Finally, the Federal Circuit held that the Board had not abused its discretion by returning the parties' briefs without consideration because Singh's briefs contained new arguments that were not raised at the outset of the interference.

## A "Classic Example" of Competing Damages Experts

*Gordon P. Klancnik*

**[Judges: Plager (author), Michel, and Lourie]**

In *Micro Chemical, Inc. v. Lextron, Inc.,* No. 02-1155 (Fed. Cir. Jan. 24, 2003), the Federal Circuit ruled that the lower court had properly performed its gatekeeping role under the Federal Rules of Evidence and did not abuse its discretion in allowing Micro Chemical, Inc.'s ("Micro Chemical") damages expert to testify. The Court further ruled that substantial evidence supported the jury's damages award.



The patent-in-suit, U.S. Patent No. 5,315,505, relates to a system for tracking the medical records of livestock. Both the Plaintiff, Micro Chemical, and the Defendants, Lextron, Inc. and Turnkey Computer Systems, Inc., provide feedlots with these systems either for free or at a substantial loss, as these systems support sales of interrelated products. After stipulating that the Defendants' unmodified systems infringe, the parties' only dispute remaining at trial related to the amount of damages.

The Defendants filed a motion to exclude testimony of the Plaintiff's expert, Edward Fiorito, arguing that Fiorito (1) based his opinion on disputed facts, and (2) misapplied the *Georgia-Pacific* factors in determining a reasonable royalty. The district court denied this motion. Using Tenth Circuit law, the Federal Circuit responded to the Defendants' first argument by explaining that it is not the role of the district court to evaluate the correctness of facts underlying one expert's testimony. In response to the second argument, the Court noted that Fiorito properly applied the *Georgia-Pacific* factors, including the effect of sales of nonpatented products on determining a reasonable royalty. Thus, according to the Court, the Defendants' contentions were without merit, and the district court did not abuse its discretion in permitting Fiorito to testify.

The Federal Circuit also affirmed the district court's rulings regarding the damages award, noting that each side presented an expert supporting its reasonable-royalty calculation. Because the jury's award hinged on which facts and whose expert was more credible, substantial evidence supported the verdict.

## Applicant Failed to Demonstrate Criticality of Claimed Range to Overcome Obviousness

*Douglas S. Weinstein*

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

In *In re Peterson*, No. 02-1129 (Fed. Cir. Jan. 8, 2003), the Federal Circuit found substantial evidence to support the Board's factual findings and affirmed the Board's conclusion of obviousness.

On December 28, 1994, Lance G. Peterson and Ioannis Vasatis (collectively "Peterson") filed U.S. Patent Application No. 08/365,392, which relates to a nickel-base single-crystal superalloy, comprising controlled quantities of rhenium, used in making industrial gas-turbine engines exposed to high temperatures. The claimed composition included, among other elements, "about 1 to 3 percent rhenium, [and] about 14 percent chromium."



The Examiner rejected the claims as obvious in light of several prior art references, including Shah; Wukusick, either alone or in view of Duhl; and Bieber in view of Wukusick. For each of these three grounds of rejection, the Examiner found a prima facie case of obviousness because of the overlapping ranges of the prior art compositions and the claimed composition. Peterson argued that the prior art did not disclose controlled quantities of rhenium and did not suggest that advantageous properties resulted from his claimed invention. The Board affirmed each ground of the Examiner's rejection.

In affirming the Board's decision, the Federal Circuit focused on the rejection based on Shah. Noting that a prima facie case of obviousness typically exists when a claimed range overlaps the ranges disclosed in the prior art, the Court compared Shah's disclosed ranges to Peterson's claimed ranges. Shah discloses superalloys having rhenium in a range of 0-7% compared to the claimed range of about 1-3%, and chromium in a range of 3-18% compared to the claimed range of about 14%. Shah's ranges clearly encompass Peterson's claimed ranges.

But, Peterson argued, it would not have been prima facie obvious to select the claimed narrower ranges from Shah's broader ranges. Dismissing this argument, the Court noted the settled case law holding that overlapping ranges establish prima facie obviousness, as do disclosed ranges close enough to the claimed ranges such that one skilled in the art would expect similar properties. Where, as here, the prior art range encompasses the claimed range, the conclusion is more compelling than in cases of mere overlap. Thus, a prior art reference that discloses a range encompassing a claimed range is sufficient to show a prima facie case of obviousness, supporting the Board's finding of prima facie obviousness.

Peterson failed to rebut the prima facie case by establishing that the claimed range achieves unexpected results relative to the prior art range. Based on examples in the specification, substantial evidence supported the Board's finding that the addition of rhenium, neither in the lower portion of the range (1%) nor in the upper portion of the range (3%), yields unexpected results.

While Peterson could have also rebutted the prima facie case by showing that the prior art taught away from the invention, he failed to do so. Many of the cited prior art references disclosed the advantages of the claimed ranges, and one, Wukusick, expressly taught that adding rhenium improves high-temperature strength.

Thus, the Federal Circuit found substantial evidence to support the Board's finding that the claimed ranges are encompassed by Shah, that Peterson failed to show unexpected results, and that the prior art did not teach away from the claimed invention.

## Court Upholds Preliminary Injunction in Sunglasses Case

*Ming-Tao Yang*

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

In *Oakley, Inc. v. Sunglass Hut International*, No. 02-1132 (Fed. Cir. Jan. 9, 2003), the Federal Circuit affirmed a district court's grant of preliminary injunction, holding that the district court did not abuse its discretion in ordering the injunction.

Oakley, Inc. ("Oakley") owns U.S. Patent No. 5,054,902 ("the '902 patent"), which claims a sunglass lens comprising three layers for producing a "vivid colored appearance" by an interference "differential effect" of light reflected from the lens. Oakley manufactures "Emerald" and "Ice" sunglasses allegedly covered by the '902 patent. Sunglass Hut International ("SHI") marketed those sunglasses for Oakley before Luxottica Group S.p.A., Oakley's largest competitor, purchased SHI. After the purchase, SHI began selling sunglasses manufactured by other Defendants. Oakley sued SHI and others (collectively "Sunglass Hut") for infringement of the '902 patent and sought a preliminary injunction. The district court first entered the preliminary injunction, enjoining the Defendants from making, using, or selling the Emerald (green) or Ice (blue) sunglasses.

On appeal, the Federal Circuit reviewed the district court's assessment of the likelihood of success concerning both invalidity and infringement. The Federal Circuit concluded that Oakley is reasonably likely to succeed on the merits at trial against all of Sunglass Hut's invalidity challenges. Raising an indefiniteness argument, Sunglass Hut first argued that the claimed phrase "vivid colored appearance," which is based on the disclosed "differential effect," is indefinite. The Court concluded, however, that even though the numerical value of the "differential effect," which is a feature that distinguished Oakley's patent over the prior art, is not defined with mathematical precision, one skilled in the art would understand the term based on the specification. Inserting its own claim construction, the Federal Circuit reasoned that the dividing line of the differential value for producing a "vivid colored appearance" must be somewhere between 2.3% and 5.45%, the values that the specification provides respectively for the prior art and for the invention.

Having so construed this limitation, the Federal Circuit affirmed the district court's finding of a likelihood of infringement.

Regarding the factors of irreparable harm and balance of hardships, the Federal Circuit concluded that the determination of the district court was not clearly erroneous. For irreparable harm, the Federal Circuit agreed that Oakley had made a sufficiently strong showing of likelihood of success on the merits to entitle Oakley to a presumption of irreparable harm. The district court's finding that Sunglass Hut was poised to release huge numbers of enjoined sunglasses also supported such presumption. For the balance of hardships, Oakley attacked Sunglass Hut's claim of irreparable harm from having to recall products, stating that Sunglass Hut admitted in its press release following the temporary restraining order ("TRO") that sales to that point had been insignificant. The Federal Circuit concluded that ample evidence supported the district court's determination that the harm to Oakley without issuance of the injunction would be greater.

Sunglass Hut also argued that the injunctive order failed to satisfy the specificity requirement of Fed. R. Civ. P. 65(d) by referring only to Oakley's trade names. The Federal Circuit ruled that the language of the order is sufficiently specific and that the reference to Oakley's trade names amounts to no more than harmless error. The Court reasoned that the purpose of Rule 65(d) is to minimize confusion and minimize needless contempt proceedings. Here, Sunglass Hut had publicly commented in a press release that the TRO, which uses the same language as the injunctive order, applied to only three models.

Concurring with the majority's opinion, Judge Dyk wrote separately to stress three points. First, he pointed out that the majority's tentative claim construction in response to the indefiniteness argument may or may not be correct. Second, he disagreed with the majority on applying a new claim construction to uphold the district court's discretionary preliminary injunction. According to Judge Dyk, the uncontradicted expert testimony in the district court is sufficient to establish a likelihood of success on infringement. Accordingly, the district court did not err in failing to provide an explicit formal claim construction when Sunglass Hut offered no claim construction. Therefore, Judge Dyk stressed that the parties at trial are free to offer new claim constructions to the district court and evidence as to why the accused lenses do or do not infringe under those claim constructions.

## Corporation Lacked Standing to Sue After Being Administratively Dissolved



*Kristin Schnell*

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

In *Paradise Creations, Inc. v. UV Sales, Inc.*, No. 02-1283 (Fed. Cir. Jan. 3, 2003), the Federal Circuit affirmed the district court's grant of SJ and dismissal of the patent-infringement claim on the ground that Paradise Creations, Inc. ("Paradise") did not have standing to file its complaint.

Paradise, a Florida corporation, became administratively dissolved under a Florida corporations statute by failing to file its annual report in 1996. Paradise had yet to regain corporate status at the time it filed its patent-infringement suit in 2000. Rather, Paradise regained its corporate status on June 29, 2001, a week after UV Sales, Inc. ("UV Sales") moved for SJ and dismissal of the complaint based on Paradise's administratively dissolved state. Paradise's standing at the time it filed suit was in question due to the alleged effect Florida corporation law had on a corporation's ability to transact business while administratively dissolved. Prior to filing the lawsuit, but during its period of dissolution, Paradise contracted for an exclusive license, allegedly sufficient to sue for infringement, under U.S. Patent 4,681,471. UV Sales argued that

Florida's corporations law gave no legal effect to that contract and, therefore, Paradise had no standing. Paradise countered that Florida's corporations law retroactively gave it standing because a state statute made the reinstatement effective on the day of the dissolution back in 1996.

The Court found that Paradise had no enforceable legal rights at the time it filed its complaint and, therefore, it had no cognizable injury, the first requirement of standing. Paradise admitted, due to its administratively dissolved status when it contracted for the license and filed the case, that it did not have legally enforceable rights to the patent at the time it filed suit, and accordingly, the Court found it did not have standing at the time it filed suit.

The Federal Circuit noted, however, that Paradise could refile now that the contractual rights to the patent under the license had legal effect, and the Court expressed no opinion about the effect of such an action.

Judge Lourie dissented, concluding that Florida law allowed the reinstatement of corporate status to give legal effect to the acts occurring during the dissolution period.





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.

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| ALJ | Administrative Law Judge |
| 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 |