

Last
month at

The Federal Circuit

FINNEGAN
HENDERSON
FAR BOW
GARRETT &
DUNNER LLPWashington, DC
202.408.4000Atlanta, GA
404.653.6400Cambridge, MA
617.452.1600Palo Alto, CA
650.849.6600Reston, VA
571.203.2700Brussels
+ 32 2 646 0353Taipei
+ 886 2 2712 7001Tokyo
+ 03 3431 6943**PATENT SPECIFICATION LIMITS CLAIM SCOPE AND SCOPE OF EQUIVALENTS**

The concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims. *Gaus v. Conair Corp.*, No. 03-1295 (Fed. Cir. Apr. 1, 2004)1

CLAIMS LIMITED TO ONLY EMBODIMENT

It is in the interests of a sound patent system and inventors, as well as the public, to hold inventors to their disclosures. *Phillips v. AWH Corp.*, No. 03-1269 (Fed. Cir. Apr. 8, 2004)2

CYCLOSPORIN "HYDROSOL" MUST BE FORMED OUTSIDE PATIENT'S BODY

While no statement in intrinsic record explicitly disclaims subject matter, the statements help guide the choice between competing dictionary definitions. *Novartis Pharms. Corp. v. Eon Labs Mfg., Inc.*, No. 03-1211 (Fed. Cir. Apr. 2, 2004)3

"CONSISTING OF" MAY NOT MEAN WHAT YOU THINK

Where a claim recites "consisting of," infringement is not avoided by the inclusion of an unrecited component when that component is "irrelevant to the invention." *Norian Corp. v. Stryker Corp.*, No. 02-1490 (Fed. Cir. Apr. 6, 2004)4

CASE OR CONTROVERSY QUESTIONABLE

The Federal Circuit reversed-in-part, vacated-in-part, affirmed-in-part, and remanded a dismissal of DJ action that was based on lack of subject matter jurisdiction. *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, No. 03-1356 (Fed. Cir. Apr. 13, 2004)5

RESTRICTIONS ON MAKING, USING, OR SELLING A SECOND-GENERATION PLANT PRODUCT DOES NOT CONSTITUTE PATENT MISUSE

Technology agreement restricting reuse of seeds from licensed crop does not improperly extend patent rights. *Monsanto Co. v. McFarling*, No. 03-1177 (Fed. Cir. Apr. 9, 2004)6

CLAIM FOR ANTIDEPRESSANT FOUND INVALID FOR PUBLIC USE

Testing the properties, uses, and commercial significance of a compound claimed solely in structural terms may start the clock under § 102(b) for filing a claim that is not limited by any property, commercially significant amount, or other use of the compound. *SmithKline Beecham Corp. v. Apotex Corp.*, No. 03-1285 (Fed. Cir. Apr. 23, 2004)8

FINDINGS OF FACT INSUFFICIENT TO SUPPORT RULING OF WILLFUL INFRINGEMENT

District court's findings of infringement are merely conclusory and fail to explain how the properly construed claims compare to the accused device. *Golden Blount, Inc. v. Robert H. Peterson Co.*, No. 03-1298 (Fed. Cir. Apr. 19, 2004)9

COURT "SHEDS LIGHT" ON CLAIM TERM "ILLUMINATING"

Absent contrary clear intent, articles "a" and "an" mean "one or more" in open-ended claims. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, No. 03-1465 (Fed. Cir. Apr. 23, 2004)10

EDITED BY | VINCE KOVALICK

Patent Specification Limits Claim Scope and Scope of Equivalents

Walter D. Davis, Jr.

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

In *Gaus v. Conair Corp.*, No. 03-1295 (Fed. Cir. Apr. 1, 2004), the Federal Circuit reversed the district court's judgment of infringement of U.S. Patent No. 4,589,047 ("the '047 patent"), wiping out a jury verdict and enhanced damages totaling more than \$37 million.

Dr. Harry Gaus charged Conair Corporation ("Conair") with infringement of the '047 patent, which is directed to a safety mechanism that prevents fatal shocks to users of electrical appliances such as hair-dryers. The patented mechanism operates by disconnecting the appliance from its power source when it comes in contact with water. More particularly, the patent describes protective circuitry that includes "a pair of spaced-apart electrically exposed conductive probe networks." When water is present, current passes through the protective circuitry. The current melts a resistance element, which stops current flow to the voltage-carrying portions of the device so that the user of the device receives no shock.

The accused device, a Conair hairdryer, includes protective circuitry that has a single sense wire that branches throughout the housing near the voltage-carrying operating elements of the device. When water is disposed between the sense wire and the electrical operating portion of the device, current flows through the protective circuit, causing the device to be disconnected from the power supply.

The Federal Circuit interpreted the asserted claim as requiring that the pair of probe networks is a distinct component separate from an electrical operating unit. The Court noted that the specification describes several ways in which the pair of probe networks and the electrical operation unit are separate. Moreover, the specification explains that "[t]he object of the invention is to devise a protective device . . . which device will respond in an extremely short time . . . independently of the operating state of the apparatus, so as to protect the user from electric shock."

The Federal Circuit further noted that the specification describes an advantage of the invention in a way that excludes the electrical operating unit from serving as part of the pair of probe networks. The specification indicates that the invention protects a user from the brief shock that is associated with prior art devices with protective circuits by arranging for the protective circuit to be separate from the voltage-carrying components of the device. This objective is achieved because the invention ensures that water will encounter the two probe networks before it encounters the voltage-carrying electrical operating unit.

The Federal Circuit thus determined that the specification shows that the invention requires that the user be completely protected from shock. Therefore, the Court reasoned, the invention cannot encompass a hairdryer with a protective device that relies on current passing between a probe and the electrical operating system, because such a device would be triggered only when the hairdryer was operating and voltage was being applied to the electrical operating system.

Having construed the claim language, the Federal Circuit addressed the issue of infringement and concluded that Conair's hairdryer does not have a pair of probe net-

works that is separate from the electrical operating unit. Accordingly, the Federal Circuit found that Conair's hairdryer does not literally infringe.

With respect to the DOE, the Federal Circuit concluded that because structure such as that in the Conair device was excluded from the scope of the claimed invention, Conair could not be infringing under the DOE. Thus, the Federal Circuit held that the Conair device does not infringe the '047 patent under the DOE, and the district court should have granted Conair's motion for JMOL of noninfringement.

[Don Dunner, Kara Stoll, and Scott Herbst of our firm successfully represented Conair in this appeal.]

Claims Limited to Only Embodiment

Darren M. Jiron

[Judges: Lourie (author), Newman, and Dyk (dissenting-in-part)]

In *Phillips v. AWH Corp.*, No. 03-1269 (Fed. Cir. Apr. 8, 2004), the Federal Circuit affirmed the district court's SJ of noninfringement that AWH Corporation, Hopeman Brothers, Inc., and Lofton Corporation (collectively "AWH") did not infringe U.S. Patent No. 4,677,798 ("the '798 patent"). The Federal Circuit found that the district court had erred in its claim construction but, ultimately, reached the same conclusion of noninfringement. The Federal Circuit also affirmed the district court's dismissal of Phillips's claim of trade-secret misappropriation against AWH.

As a key issue in the case, the Federal Circuit, like the district court, focused on the

construction of the term "baffle." The '798 patent relates to building modules adapted to fit together for the construction of fire, sound, and impact-resistant security barriers. These modules include "means disposed inside [a] shell for increasing its load bearing capacity comprising internal steel baffles extending inwardly from the steel shell walls," as recited in claim 1. The disclosure of the '798 patent describes and illustrates the baffles as angled members deployed from the shell walls at angles of other than 90 degrees. The claims, however, do not include limitations relating to the angle at which the baffles meet the shell walls.

The district court concluded that claim 1 of the '798 patent includes means-plus-function language invoking 35 U.S.C. § 112, ¶ 6, and, therefore, limited the term "baffles" to the angled structures disclosed in the specification that extend from the shell walls at angles other than 90 degrees. The district court's SJ of noninfringement followed in view of AWH's baffles that met the shell walls at an angle of 90 degrees.

While the Federal Circuit found that the district court improperly relied upon § 112, ¶ 6 to construe the term "baffles," the Federal Circuit reached the same conclusion with respect to noninfringement. Reading the term "baffles" in view of the specification, the Federal Circuit concluded that the term "baffles" must extend from the shell walls at acute or obtuse angles other than 90 degrees. The Court observed that the only embodiment disclosed in the '798 patent includes baffles angled at acute or obtuse angles with respect to the shell walls. With no other embodiments disclosed, the Court concluded that the angled baffles are the actual invention and not just a preferred embodiment. Also, the Federal Circuit found that the baffles of the '798 patent must be angled with respect to the shell walls to accomplish one of the stated goals of deflecting projectiles.

Thus, despite a recognized plain meaning of the term “baffles,” the Federal Circuit looked to the disclosure of the ‘798 patent and narrowly construed the term “baffles” to include elements described in the specification but not included in the claims.

In dissent, Judge Dyk argued that this claim construction went against established precedent and constituted an improper incorporation into the claims of structural details of the disclosed preferred embodiment.

With respect to Phillips’s claim of trade-secret misappropriation, the Federal Circuit agreed with the district court that the claim was time-barred by the statute of limitations clause set forth by the governing state law.

page | 03

Cyclosporin “Hydrosol” Must Be Formed Outside Patient’s Body

M. Andrew Holtman

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

In *Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc.*, No. 03-1211 (Fed. Cir. Apr. 2, 2004), the Federal Circuit affirmed the district court’s grant of SJ that U.S. Patent No. 5,389,382 (“the ‘382 patent”) was not infringed by Eon Labs Manufacturing, Inc.’s (“Eon”) manufacture and sale of tablets.

The ‘382 patent, owned by Novartis Pharmaceuticals Corporation (“Novartis”), provides a formulation for cyclosporin that addresses problems inherent with the use of the drug. Cyclosporin is an immunosuppressive drug used to reduce the risk of organ rejection after transplantation. The drug’s application, however, was limited by its low solubility in water, which made it less absorbable in the human body. The ‘382

patent provides cyclosporin as a hydrosol, which is more soluble.

The principal issue on appeal was whether the meaning of “hydrosol,” as used in the claims of the ‘382 patent, is limited to medicinal products prepared outside the body or includes products formed within the stomach of the patient upon ingestion. This distinction is decisive since neither party disputed that Eon’s tablet is hydrosol-free prior to ingestion by the patient. The district court’s claim interpretation required a meaning of the term “hydrosol” to exclude conversion in the patient’s stomach.

The Federal Circuit began its claim-construction analysis with an examination of a general purpose dictionary. It determined that a definition of “hydrosol” yields two competing definitions: (a) a medicinal preparation consisting of a dispersion of solid particles in an aqueous colloidal solution prepared outside the body, or (b) a dispersion of solid particles in aqueous colloidal solution formed in a patient’s stomach. Thus, the term “hydrosol” is ambiguous.

To resolve the dispute, the Court looked to the intrinsic record. It noted that the specification consistently refers to the hydrosol of the ‘382 patent in terms of a “pharmaceutical” composition. A “pharmaceutical” is defined in the dictionary as a “medicinal drug,” which, according to the Federal Circuit, is a drug that necessarily must be made outside the body. The Court pointed to an additional claimed aspect of the hydrosol—an intravenous injection form—as further support of this definition.

Lastly, the Federal Circuit considered the prosecution history. It concluded that because Novartis had previously argued before the PTO to overcome an obviousness rejection that the drug was of a size sufficient to be administered by intravenous injection, it too supports the narrower definition of the term “hydrosol.”

Having determined that the narrower meaning of the term “hydrosol” applied, the Court found no direct infringement of the ‘382 patent. And, because there can be no induced or contributory infringement without the underlying direct infringement, the Federal Circuit affirmed the district court’s grant of SJ against Novartis. The Court also affirmed the district court’s grant of SJ of no infringement under the DOE because a holding to the contrary would vitiate the claimed requirement that the dispersion be prepared outside the body.

Judge Clevenger disagreed with the majority’s use of the tools of claim interpretation. He argued that hydrosol must be given its full breadth of meaning, absent the patentee’s clear disavowal of scope that alters the ordinary meaning, and that the patentee was denied that interpretation when the majority chose to construe terms further removed from the term at issue.

“Consisting Of” May Not Mean What You Think

Anthony A. Hartmann

[Judges: Newman (author), Friedman, and Schall (dissenting-in-part)]

In *Norian Corp. v. Stryker Corp.*, No. 02-1490 (Fed. Cir. Apr. 6, 2004), the Federal Circuit affirmed-in-part and reversed-in-part various pre- and post-trial rulings of the district court regarding Norian Corporation’s (“Norian”) U.S. Patent Nos. 5,336,264 and 6,002,065 (“the ‘264 patent” and “the ‘065 patent,” respectively).

Both patents are generally directed to certain rapidly setting calcium phosphate compositions (cements) for the repair of bones or teeth. The ‘264 patent claims methods of preparing these compositions comprising, inter alia, combining a calcium

source, a phosphoric acid source, and a lubricant. The ‘065 patent claims recite kits for preparing these compositions “consisting of” at least one calcium source, at least one phosphoric acid source, and a solution consisting of water and a sodium phosphate.

Norian filed suit against Stryker Corporation (“Stryker”), alleging willful infringement by Stryker’s BoneSource® kit, which comprised a sodium phosphate component, a mixture of tetracalcium phosphate and dicalcium phosphate, a spatula, and instructions for combining the components.

The district court had found the specification’s use of “phosphoric acid source,” the only disputed term, to be different from its natural reading and construed the term to mean “an acid chemical that acts as a source of phosphate.” The Federal Circuit affirmed, in view of the specification and the lack of a contradictory prosecution history.

After affirming a jury determination that the claims of the ‘264 patent were obvious, the Federal Circuit addressed the district court’s denial of a motion for new trial on obviousness. Norian contended prejudice due to the jury having heard evidence of Norian’s misstatements to the PTO during prosecution of the ‘264 patent. Specifically, Norian’s counsel had admitted that a factual misstatement had been made regarding the prior art. While the district court ruled in a SJ determination that this did not constitute inequitable conduct, it instructed the jury to consider such evidence. The district court explained that “it was for purposes of allowing the jury to test the strength of the presumption that goes with the presumption of validity . . . whether or not the examiner really did understand what he was ruling”

The Federal Circuit noted that introspection and speculation into the Examiner’s understanding of the prior art or the correctness of the examination process is not

part of the objective review of patentability. However, while the Court concluded that the district court had erred in the jury instructions, it noted that the motion for new trial was denied because Norian had failed to object to the instructions. In view of the failure to object and the entirety of the prosecution history, the Court affirmed the denial of a new trial.

With respect to anticipation, the Federal Circuit affirmed the district court's ruling that the claims of the '264 patent are not anticipated by a certain extended abstract ("the Abstract"). The parties agreed that the Abstract described the '264 patent invention; however, Norian argued that the Abstract was not a publication under 35 U.S.C. § 102, because it was available only upon individual request to the authors. The Federal Circuit agreed that there was a lack of substantial evidence presented of dissemination of the Abstract.

The Federal Circuit reviewed the grant of Stryker's SJ motion of noninfringement of the '065 patent. The district court had held "consisting of" to mean that kits include nothing beyond what is claimed and ruled that Stryker's kit, which included a spatula, did not infringe as a matter of law. The Federal Circuit reversed and remanded, finding that the term "consisting of" permits no other chemicals in the kit, but that a spatula is not part of the invention that is described.

Judge Schall dissented from this finding of no infringement, explaining that it was inconsistent with the Court's precedent, which precludes all components, and the public-notice function of patent claims. Judge Schall noted that there is nothing in the prosecution history to justify the majority's claim construction and that Norian could easily have written the claims to permit mechanical components, but chose not to.

Finally, the Federal Circuit reviewed the district court's grant of JMOL, dismissing the issue of willfulness after Norian had presented its case-in-chief. The Court noted

that there is no evidentiary presumption of willfulness and it was not enough that Stryker had stipulated that it had knowledge of the Norian patents. The Federal Circuit agreed that Stryker never had the burden to rebut willfulness, since Norian never presented a prima facie case of willful infringement.

Case or Controversy Questionable

Aryn D. Davis

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

In *Sierra Applied Sciences, Inc. v. Advanced Energy Industries, Inc.*, No. 03-1356 (Fed. Cir. Apr. 13, 2004), the Federal Circuit reversed-in-part, vacated-in-part, affirmed-in-part, and remanded a dismissal of a DJ action that was based on lack of subject matter jurisdiction.

Sierra Applied Sciences, Inc. ("Sierra") sued Advanced Energy Industries, Inc. ("AEI"), seeking a declaration that AEI's U.S. Patent No. 5,718,813 ("the '813 patent") is invalid and not infringed by Sierra's 2 kilowatt and 150 kilowatt reactive-sputtering power supplies. The district court dismissed the action for lack of a case or controversy.

The Federal Circuit, in reviewing the record, decided on its own initiative that three power sources were actually at issue—the 2 kW device and two prototype versions of the 150 kW device. The Court then separately addressed whether a case or controversy existed as to each of the three power supplies. It asked whether, for each device, there was (a) an explicit threat or other action by the patentee creating a reasonable apprehension of an infringement suit, and (b) present activity by the alleged infringer that could constitute infringement or con-

crete steps taken with intent to conduct such activity.

The Federal Circuit found the first prong satisfied for all three devices because AEI's letters to Sierra threatening suit were broad enough to create a reasonable apprehension that AEI would assert the '813 patent against all of Sierra's power supplies for all of Sierra's activities. For the second prong of the test, the Court reached a different conclusion for each of the three power supplies.

The Federal Circuit noted that assurances by AEI's counsel in the district court proceedings that AEI would not sue for Sierra's in-house use of the 2 kW device alleviated any controversy as to the use. Those assurances were not, however, broad enough to alleviate Sierra's apprehension of suit for several sales of the 2 kW device, which though de minimis and occurring several years before the complaint, were within the six-year limitations period and, thus, supported jurisdiction.

The Court found that the first of the two 150 kW prototypes was destroyed before or during testing, then abandoned. The record was unclear as to whether the first 150 kW prototype was used before it was destroyed. The Court remanded, instructing that if the device worked, even briefly, the testing was sufficient to satisfy the "infringing activity" prong of the case or controversy test.

As to the second 150 kW prototype, the Court found that, because it was undisputed that Sierra had not engaged in infringing activity with the second 150 kW prototype before the filing of the complaint, jurisdiction depended on whether Sierra had taken "concrete steps" with the intent to engage in infringing activity with respect to the second 150 kW prototype. The Court focused on two necessary factors: "immediacy," i.e., the period of time between the date the complaint was filed and the date on which

the infringing activity will begin, and "reality," i.e., whether the design of the potentially infringing device is substantially fixed on the date of the complaint. The one-year period between the complaint and the completion of the second 150 kW prototype was too long to show "immediacy" at the time of the filing. Furthermore, Sierra was unable to show "reality," since at the time of the complaint, the design of the second 150 kW prototype was fluid and indeterminate. As a result, no case or controversy existed as to the second 150 kW prototype.

Restrictions on Making, Using, or Selling a Second-Generation Plant Product Does Not Constitute Patent Misuse

Kakoli Caprihan

[Judges: Clevenger (author), Lourie, and Plager]

In *Monsanto Co. v. McFarling*, No. 03-1177 (Fed. Cir. Apr. 9, 2004), the Federal Circuit affirmed a district court's findings that Homan McFarling had breached a technology agreement he had signed with Monsanto Company ("Monsanto") when he replanted some soybeans he had purchased pursuant to the agreement, and that McFarling had failed to demonstrate a genuine issue of material fact on his counterclaims or defenses to Monsanto's breach of contract claims. However, the Court vacated and remanded the district court's judgment relating to damages.

The two patents-in-suit relate to genetic-modification technology in the field of soybean seeds. Monsanto manufactures ROUNDUP® herbicide, which contains glyphosate, a chemical that kills vegetation by inhibiting a particular enzyme: 5-enolpyruvyl-shikimate-3-phosphate synthase

("EPSPS"). Monsanto also markets ROUNDUP READY®, which operates by inserting the gene sequence for a variant of EPSPS that is not affected by the presence of glyphosate but still performs its enzymatic function. Therefore, ROUNDUP® can be sprayed on a field where ROUNDUP READY® soybeans have been planted, killing weeds but leaving the soybeans intact. Monsanto's U.S. Patent No. 5,633,435 ("the '435 patent") and Patent No. 5,325,605 ("the '605 patent") relate, respectively, to the gene encoding the modified EPSPS enzyme and to the use of a particular promoter in genetically modified plant cells.

Monsanto licenses its ROUNDUP READY® technology through two interrelated licensing schemes. First, it licenses the patented gene to seed companies that manufacture the glyphosate-tolerant seeds that are sold to farmers. Second, Monsanto requires that seed companies execute licenses, rather than conduct unconditional sales, with their farmer customers.

The 1998 version of the Monsanto Technology Agreement (the "Technology Agreement") between Monsanto and the farmers using ROUNDUP READY® soybeans places several conditions on the farmers' use of the licensed soybeans. For example, the farmers are only allowed to use the seed containing the Monsanto gene technologies in a single season, and they cannot save any crop produced from this seed for replanting. The Technology Agreement also contains a liquidated-damages clause. In the event of a breach, the damages will include a claim for liquidated damages based on 120 times the applicable technology fee.

McFarling, a farmer in Mississippi, executed the Technology Agreement and licensed 1000 bags of ROUNDUP READY® soybeans. He concedes that he saved 1500 bushels of seed from his 1998 crop and then replanted them in 1999.

As a result, Monsanto filed suit against McFarling, alleging, among other things,

infringement of the '435 and '605 patents and breach of the Technology Agreement. McFarling's affirmative defenses included patent misuse, antitrust, and the Plant Variety Protection Act ("PVPA"). The district court granted SJ in favor of Monsanto on all of McFarling's affirmative defenses, as well as on liability with respect to the '605 patent-infringement claim and the breach of contract claim. As to the damages claim, the district court entered final judgment on Monsanto's breach of contract claim in a specified amount only after McFarling had stipulated that he purchased 1000 bags of Monsanto's soybean seeds. The district court fashioned its own formula to use the multiplier in the liquidated-damages clause.

The Federal Circuit affirmed the district court's grant of SJ against McFarling's patent-misuse affirmative defense. McFarling argued that Monsanto had committed patent misuse because it had impermissibly tied an unpatented product to a patented product. Specifically, by prohibiting farmers from saving seeds, McFarling argued that Monsanto had extended its patent on gene technology to include an unpatented product—the germplasm, or "God-made" soybean seed. The Federal Circuit held that this was not a tying arrangement. The Technology Agreement did not impose a restriction on the use of the product purchased under the license, but instead imposed a restriction on the use of the goods made by the licensed product. However, in this case, the licensed and patented product (the first-generation seeds) and the goods made by the licensed product (the second-generation seeds) are nearly identical copies. Since Monsanto's '435 patent reads on the first-generation seeds, it would also read on the second-generation seeds; therefore, the restrictions in the Technology Agreement prohibiting the replanting of the second-generation ROUNDUP READY® soybeans do not impermissibly broaden Monsanto's rights under

the patent statute. The Federal Circuit also rejected McFarling's antitrust counterclaim for the same reasons.

Additionally, the Court refused to reconsider its previous ruling that the PVPA does not preempt and invalidate all prohibitions on seed saving contained in utility-patent licenses. The Federal Circuit maintained that the right to save seeds of plants registered under the PVPA does not impart the right to save seeds of plants patented under the Patent Act. The two statutes can mutually coexist and Congress did not intend for exemptions to exist for saving seeds under a utility patent or prohibit owners of utility patents from enforcing seed-saving prohibitions in their licenses.

However, the Federal Circuit did vacate the district court's damages award. The Court held that under Missouri law, the provision in the Technology Agreement applying a 120 multiplier to the technology fee is an unenforceable and invalid penalty clause. Accordingly, the Court remanded the judgment of damages to the district court for determination of actual damages.

Claim for Antidepressant Found Invalid for Public Use

Scott J. Popma

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

In *SmithKline Beecham Corp. v. Apotex Corp.*, No. 03-1285 (Fed. Cir. Apr. 23, 2004), the Federal Circuit rejected the district court's claim construction that led to a SJ of noninfringement, but affirmed the SJ nonetheless, concluding that the claimed invention was invalid as having been in public use.

This appeal arose from an ANDA infringement action involving Paxil®, an antidepressant marketed by SmithKline Beecham Corporation ("SB"). Claim 1 of SB's U.S. Patent No. 4,721,723 ("the '723 patent") claims "crystalline paroxetine hydrochloride hemihydrate." Paxil® contains paroxetine hydrochloride ("PHC") in the hemihydrate crystalline form. Apotex Corporation ("Apotex") sought to make a generic version of PHC, arguing that its PHC product was in an anhydrate crystalline form. SB alleged that Apotex's proposed product would contain the patented hemihydrate crystalline form and would therefore infringe claim 1 of the '723 patent.

The district court interpreted claim 1 as limited to PHC hemihydrate in "commercially significant" amounts and found that such amounts would have to be in the "high double digits." The district court supported this claim construction with a reference in the specification to the hemihydrate's superior handling properties. The district court then found that Apotex's proposed paroxetine drug did not contain commercially significant amounts of PHC hemihydrate and, therefore, would not infringe.

SB had argued that the claim covered a crystalline form of PHC that contains one molecule of bound water for every two molecules of PHC in the crystalline structure, and that any PHC that had this crystalline structure would infringe this claim. The district court found that such a claim construction would be indefinite.

The Federal Circuit disagreed with the district court's claim construction, stating that claim construction "is not a policy-driven inquiry. . . . it is a contextual interpretation of language. The scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning." *Slip op.* at 11. The Federal

Circuit then found that claim 1 covered any amount of PHC hemihydrate. The Federal Circuit also rejected the district court's indefiniteness arguments, observing that the test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention. The Federal Circuit found that the scope of the claim is in fact clear to one of ordinary skill. The Federal Circuit then adopted the district court's factual finding that Apotex's PHC anhydrate would contain PHC hemihydrate, and found that under the correct claim construction, Apotex would infringe claim 1.

The Federal Circuit then turned to the public-use issue. The district court had granted SB's motion for SJ that SB's PHC clinical trials did not constitute a public use but rather were experimental. But, the Federal Circuit reversed. The Court assumed that the clinical trials were subject to satisfactory controls and otherwise properly conducted to fulfill their intended purpose—namely, to establish the efficacy and safety of PHC hemihydrate as an antidepressant drug for humans. Nevertheless, the Federal Circuit found that SB's clinical trials could not be experimental, because the intended use of PHC was not recited in the claim. The Court warned that “a patentee should understand that testing the properties, uses, and commercial significance of a compound claimed solely in structural terms may start the clock under § 102(b) for filing a claim that is not limited by any property, commercially significant amount, or other use of the compound.” *Slip op.* at 23.

In a concurring opinion, Judge Gajarsa disagreed with the majority ruling on public-use invalidity, citing precedent that had found experimental use even where the intended use was not literally recited in the claim. Judge Gajarsa instead concluded that the Court should hold that patent claims drawn broadly enough to encompass prod-

ucts that spread, appear, and reproduce through natural processes are not patentable and invalid under 35 U.S.C. § 101, and that claim 1 of the '723 patent was such a claim.

Findings of Fact Insufficient to Support Ruling of Willful Infringement

John W. Cox

[Judges: Linn (author), Mayer, and Newman (concurring-in-part and dissenting-in-part)]

In *Golden Blount, Inc. v. Robert H. Peterson Co.*, No. 03-1298 (Fed. Cir. Apr. 19, 2004), the Federal Circuit affirmed a district court's claim construction and finding of validity, but remanded the issue of infringement.

Golden Blount, Inc. (“Blount”) and Robert H. Peterson Company (“Peterson”) compete in the fireplace-equipment market. Blount owns the patent-in-suit, U.S. Patent No. 5,998,159 (“the ‘159 patent”), which relates to a gas-fired, artificial log and coal-burner assembly.

Blount alleged infringement by a device marketed by Peterson—the EMB Series Ember Flame Booster (“Booster”) based on the function and relative positions of the Booster's burners. Claim 1 recites that a support means holds “the elongated primary burner in a raised level relative to the forwardly position secondary coals burner elongated tube.” The district court had found that “raised level” meant that the primary burner was at a raised level relative to the secondary burner. Peterson argued that the raised level should be based on the position of the gas ports, but the Federal Circuit agreed with the district court.

Claim 17 recites that the gas ports are directed “away from the fireplace opening.”

The district court had construed this to mean any direction that did not include a horizontal component pointed toward the vertical plane of the fireplace opening, and the Federal Circuit affirmed.

Based on its claim constructions, the district court had concluded that Peterson infringed each of the asserted claims. It had also concluded, among other things, that the claims of the patent are valid and that Peterson's infringement was willful.

The Federal Circuit vacated and remanded the infringement issues because the district court did not provide findings of fact to support a conclusion of infringement. With a lack of support for findings of infringement, the Federal Circuit could not determine whether the trial court had any evidence to support its conclusions, nor was it able to determine whether the district court applied appropriate legal standards. Because it remanded the infringement issues, the Court also vacated the finding of willfulness.

The Federal Circuit also found that Peterson did not meet its burden of proving invalidity by clear and convincing evidence. The Court found that Peterson offered only the bare assertion that the patent claims would have been obvious. The Court stated that it therefore had no reason to reverse the district court's conclusion that the '159 patent is not invalid. The Federal Circuit found that Peterson had failed to raise an inequitable-conduct issue before the district court and, as a result, had waived that issue.

Judge Newman concurred-in-part and dissented-in-part. She concurred with the court's finding of validity and that evidence to support Peterson's inequitable-conduct claim was lacking, but dissented against remanding for another determination of infringement. She based her dissent on judicial efficiency and a finding of sufficient support in the record, stating that the issues on appeal were decided by the claim-construction issue and did not require a remand for a longer opinion.

Court "Sheds Light" on Claim Term "Illuminating"

James J. Boyle

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

In *Scanner Technologies Corp. v. ICOS Vision Systems Corp.*, No. 03-1465 (Fed. Cir. Apr. 23, 2004), the Federal Circuit vacated and remanded the district court's SJ ruling that ICOS Vision Systems Corporation, N.V. ("ICOS") did not infringe U.S. Patent Nos. 6,064,757 ("the '757 patent") and 6,064,756 ("the '756 patent").

Scanner Technologies Corporation ("Scanner") owns the '757 and '756 patents, which are directed to methods and systems, respectively, for electronic-component inspection. The patents disclose the application of triangulation techniques using images of an illuminated Ball Grid Array ("BGA") device to determine the precision to which solder balls in the BGA device are at the same height. Among other elements, claim 1 of the '757 patent recites the step of "illuminating" and claim 1 of the '756 patent recites "an illumination apparatus." The district court construed both uses of the term as being limited to only one illumination source. The district court recognized that the phrase "illumination source" appears nowhere in the claims of the '756 patent, but concluded that the difference between the correct claim term "illumination apparatus" and the phrase "illumination source" was not significant for purposes of the claim construction. On the basis of this construction, the district court ruled under SJ that ICOS did not infringe the '757 and '756 patents.

On appeal, the Federal Circuit held that the district court's imprecise use and apparent construction of the phrase "illumination source" was harmless error because the district court had made clear that its decision and reasoning applied to the actual claim language.

The Federal Circuit also considered whether the district court failed to account for the difference between a system claim and a method claim when it concurrently construed, and limited, an apparatus-claim term and a method-claim term together. The Court concluded that the district court did appreciate the difference between a system claim and a method claim, and ruled that the apparatus “an illumination source” and step “illuminating” may be properly construed together.

Notwithstanding the holdings above, the Federal Circuit concluded that the district court had erred by limiting these claim terms to only a single illumination source. The Federal Circuit reiterated that a patentee must evince a clear intent to limit the

articles “a” and “an” to mean “only one” when used in an open-ended claim that contains the transitional phrase “comprising.” The Federal Circuit found no evidence of such clear intent in the prosecution or claims of the ’757 and ’756 patents.

DISCLAIMER:

The case summaries reflect the understanding of the authors only and are not meant to convey legal opinions or advice of any kind. The firm disclaims any liability for any errors or omissions in these summaries. This promotional newsletter does not establish any form of attorney-client relationship with our firm or with any of our attorneys.

In **Last month at The Federal Circuit**, certain terms, titles, and names of federal agencies that are frequently referred to in text, appear in abbreviated forms or as acronyms. These abbreviated forms and acronyms are listed below.

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Board of Patent Appeals and Interferences
Commissioner	Commissioner of Patents and Trademarks
CIP	Continuation-in-Part
DJ	Declaratory Judgment
DOE	Doctrine of Equivalents
FDA	Food & Drug Administration
IDS	Information Disclosure Statement
IP	Intellectual Property
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SEC	Securities and Exchange Commission
SJ	Summary Judgment
SM	Special Master