

Last Month at the Federal Circuit

October 2006

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- This month, the Federal Circuit addressed claim construction under 35 U.S.C. § 112, ¶ 6, in *Massachusetts Institute of Technology v. Abacus Software*, Nos. 05-1142, -1161, -1162, -1163 (Fed. Cir. Sept. 13, 2006), finding one claim term invoked § 112, ¶ 6, and another did not. Specifically, the Court held that the claim term “colorant selection mechanism” warranted § 112, ¶ 6, treatment, whereas “aesthetic correction circuitry” did not.
- In *Alza Corp. v. Mylan Laboratories, Inc.*, No. 06-1019 (Fed. Cir. Sept. 6, 2006), the Federal Circuit addressed its “motivation-suggestion-teaching” test for obviousness, stating that “[t]here is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art.” Slip op. at 6 (emphasis in original). Meanwhile, the Supreme Court will consider the test for obviousness in November when it hears *KSR International Co. v. Teleflex, Inc.*, No. 04-1350. In that case, the Solicitor General characterized the Federal Circuit’s application of its “motivation-suggestion-teaching” test for obviousness as “rigorous and inflexible.”

Motivation to Combine Prior Art Teachings Need Not Be Found in the Art

Hilary D. Lang

Judges: Gajarsa (author), Clevenger, Prost

[Appealed from N.D. W. Va., Judge Keeley]

In *Alza Corp. v. Mylan Laboratories, Inc.*, No. 06-1019 (Fed. Cir. Sept. 6, 2006), the Federal Circuit affirmed the district court’s holding that the asserted claims of U.S. Patent No. 6,124,355 (“the ’355 patent”) were invalid under 35 U.S.C. § 103(a) and not infringed.

Alza Corporation (“Alza”) owns the ’355 patent, which discloses an oral once-a-day extended-release oxybutynin formulation for the treatment of urinary incontinence. In describing the technology, the Court noted that an oral drug dissolves in the gastrointestinal (“GI”) tract and is absorbed into the bloodstream. A drug formulation may be released in the stomach, or it may have an extended release such that it is released slowly as it passes through the GI tract, resulting in the release of some of the drug in the colon. The Court explained that if the colon cannot absorb a particular drug, then there

would be no reason to develop such an extended-release formulation. Claim 2, which is representative of the ’355 patent, is directed to “a sustained-release oxybutynin formulation,” which delivers specified amounts of the drug over specified periods of time for up to twenty-four hours. Alza markets the patented formulation as Ditropan XL®. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively “Mylan”) filed two ANDAs for a generic version of Ditropan XL®, and Alza sued.

In its *Markman* Order, the district court construed the term “deliver” to refer to the rate of *in vivo* release of oxybutynin in the GI tract. To prove that Mylan’s ANDA formulation infringed the ’355 patent, Alza presented evidence showing (1) the rate at which Mylan’s formulation released oxybutynin in an *in vitro* dissolution apparatus, and (2) the rate at which Mylan’s formulation resulted in the accumulation of oxybutynin in the bloodstream. Alza, however, did not provide any direct evidence that Mylan’s formulation released oxybutynin in the GI tract at the claimed rates. Thus, the district court found that Alza failed to meet the burden of proof for infringement. Additionally, the district court found that the asserted claims of the ’355 patent were both obvious over and anticipated by the prior art. Alza appealed.

The Federal Circuit first addressed obviousness, noting that obviousness is a question of law based on underlying factual questions. These underlying factual inquiries, as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), include the scope and content of the prior art, the level of ordinary skill in the prior art, and the difference between the claimed invention and the prior art.

The Court reiterated that hindsight reasoning, based on the teachings of the invention at issue, may not enter an obviousness analysis. The secondary indicia of nonobviousness discussed in *Graham* serves to prevent such improper hindsight reasoning. Similarly, the “motivation to combine” analysis prevents improper hindsight reasoning by requiring that a court consider “whether a person of ordinary skill in the art, possessed with the . . . problem facing the inventor, would have been led to make the combination recited in the claims.” Slip op. at 5 (citation omitted). Thus, the “motivation-suggestion-teaching” test incorporates both the “scope and content of the prior art” and the “level of ordinary skill in the pertinent art,” as required by *Graham*. *Id.* Nevertheless, the Court emphasized that its “motivation-suggestion-teaching” test does not require an actual teaching in the prior art in order to establish that one of ordinary skill in the art would have known to combine references. Rather, “[t]here is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art.” *Id.* at 6 (emphasis in original).

On appeal, the Federal Circuit affirmed the district court’s holding of invalidity on obviousness grounds, and did not reach the issue of anticipation. The Court rejected Alza’s argument that one of ordinary skill in the art would not have been motivated to adapt the prior art teachings to the oxybutynin because no one would expect that an extended-release formulation of oxybutynin would have any therapeutic value, in particular because nothing in the prior art references supported the idea that

lipophilicity of a drug correlated to its colonic absorptivity. Instead, the Court emphasized that the motivation to combine references for a finding of obviousness can be found in the knowledge of one of ordinary skill in the art, and relied on the testimony of Mylan’s expert, Dr. Amidon, that at the time of the invention, he would have expected oxybutynin to be rapidly absorbed in the colon based on its lipophilicity. The Court explained that expert testimony may establish the knowledge of one of ordinary skill in the art at the time of the invention.

The Federal Circuit further rejected Alza’s contention that two additional prior art references negated

Dr. Amidon’s testimony regarding knowledge in the art. The Court explained that at best, the references Alza presented suggested that other factors, in addition to lipophilicity, affect a drug’s absorption behavior in the colon. Thus, the Court found no clear error in the district court’s findings. Additionally, the Court agreed with the district court’s conclusion that one of ordinary skill in the art would have had a reasonable expectation of success in combining the prior art teachings. Finally, the Federal Circuit found no clear error in the district court’s finding that Alza failed to establish secondary indicia of nonobviousness.

“We do not have a rigid test that requires an actual teaching to combine before concluding that one of ordinary skill in the art would know to combine references.” Slip op. at 6.

Despite its invalidity holding, the Federal Circuit analyzed Alza’s infringement. The Court noted that Alza provided no direct evidence at trial on the rate of release of the accused product *in vivo*. The Federal Circuit explained that Alza had “failed to credibly link [the indirect evidence it offered] with the relevant pharmacokinetic parameter—the rate of *in vivo* dissolution in the GI tract.” *Id.* at 16. At trial, Alza attempted to equate the oxybutynin blood plasma concentrations with the claimed *in vivo*

dissolution rates, but the only evidence in support of this contention was a statement by Dr. Amidon, which he had promptly recanted. Thus, the Federal Circuit agreed with the district court that the plasma concentration data failed to establish the *in vivo* release rate of the ANDA formulation. Alza's *in vitro* dissolution rate data was similarly inadequate. The district court had relied on Dr. Amidon's testimony that the *in vitro* experiments did not reflect the *in vivo* behavior of the drug. Thus, the Federal Circuit concluded that the *in vitro* dissolution rates were not relevant to infringement.

Finally, the Federal Circuit "explicitly reject[ed]" Alza's argument that the district court erred because it did not expressly state that not only was the *in vitro* and blood plasma data insufficient on its own, but the combination of data was also insufficient to establish infringement. The Court noted that in this case, each piece of evidence was "severely inadequate" and, therefore, the combination of the two pieces of evidence was likewise insufficient to establish infringement. Thus, Alza had failed to establish infringement.

"Colorant Selection Mechanism" Construed Under § 112, ¶ 6, but "Aesthetic Correction Circuitry" Connotes Sufficient Structure to Avoid § 112, ¶ 6

Bradley E. Edelman

Judges: Michel (dissenting), Friedman, Dyk (author)

[Appealed from E.D. Tex., Judge Folsom]

In *Massachusetts Institute of Technology v. Abacus Software*, Nos. 05-1142, -1161, -1162, -1163 (Fed. Cir. Sept. 13, 2006), the Federal Circuit vacated and remanded the district court's grant of SJ of noninfringement of U.S. Patent

No. 4,500,919 ("the '919 patent"), finding that the district court erred in its claim construction and improperly excluded Microsoft Windows ("Windows") as an infringing product.

"The generic terms 'mechanism,' 'means,' 'element,' and 'device,' typically do not connote sufficiently definite structure."
Slip op. at 14.

Massachusetts Institute of Technology ("MIT"), owner of the '919 patent for a system for reproducing copies of a color original image, and its exclusive licensee, Electronics for Imaging, Inc. ("EFI"), sued Microsoft Corporation ("Microsoft") and other defendants, alleging that their products, including Windows, infringed MIT's '919 patent. After the district court construed the claims, the parties stipulated to a final judgment of noninfringement.

On appeal, the Federal Circuit first agreed with the district court that the claimed "scanner" must have "relative movement between the scanning element and the object being scanned." Against MIT's urging, the Court held that the claimed "scanner" did not cover a camera used to photograph an image to be reproduced. The Court relied first on the specification, which only described one type of scanner that worked by moving an original image past a scanning element. Looking next to dictionary definitions, the Court recited two dictionaries that described scanning as including relative movement between a scanning device and an original. Based on this evidence, the Court upheld the district court's construction of the term "scanner" as requiring relative movement between the scanning element and the object being scanned.

The Federal Circuit also agreed with the district court that the claimed "scanner" must involve placing the color original on or in close proximity to the scanner. The Court concluded that the district court properly relied on the '919 patent specification, expert testimony, and

technical references in concluding that a person of ordinary skill in the art at the time of the invention would have known of two general types of scanners, both of which required close proximity between the color original and the scanner. The Court thus agreed that the term scanner “should be defined by what was known in the art at the time.” Slip op. at 13.

The Court then found that the term “colorant selection mechanism” implicated 35 U.S.C. § 112, ¶ 6. The Court first noted that terms such as “mechanism,” “means,” “element,” and “device” typically do not connote sufficiently definite structure to invoke § 112, ¶ 6. *Id.* at 14. The Court then cited *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1360 (Fed. Cir. 2004), which states that § 112, ¶ 6, does not apply to “a term that is simply a nonce word or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term ‘means for.’” *Id.* Based on the ’919 patent claims, which used the term “colorant selection means” synonymously with “colorant selection mechanism,” dictionary definitions, one of which defined “mechanism” as “means,” and the lack of any standard meaning of the term “colorant selection” in the art, the Court agreed with the district court that the term “colorant selection” did not connote a sufficiently definite structure to avoid § 112, ¶ 6.

Next, the Court disagreed with the district court’s conclusion that “aesthetic correction circuitry” should be construed under § 112, ¶ 6. The Court found that, in contrast to the term “mechanism,” dictionary definitions establish that the term “circuitry,” by itself, connotes structure. Moreover, the Court found that the claim language here did not merely describe a circuit, it added further structure by describing the operation of the circuit. Based on this analysis, the Court held that the claimed “aesthetic correction circuitry” did not implicate § 112, ¶ 6. However, the Court limited the meaning of “circuitry” to encompass only hardware, not including software, in light of the specification’s repeated description of employing only hardware and dictionary definitions of “circuitry.”

Finally, the Court found that the district court erred in refusing to allow MIT to update its preliminary infringement contentions. Over one year after MIT had served its preliminary infringement contentions, the district court issued an order noting for the first time that preliminary infringement contentions are deemed to be final and can only be amended by a showing of good cause. The district court relied on this order in refusing to allow MIT to amend its preliminary infringement contentions to include Windows. The Federal Circuit reversed, finding that MIT had not been given sufficient notice that its preliminary infringement contentions would be deemed final or that they could only be updated upon a showing of good cause.

In dissent, Judge Michel stated that “aesthetic correction circuitry” was correctly construed as a means-plus-function limitation because the limitation failed to recite sufficiently definite structure. Furthermore, Judge Michel exclaimed that excluding Windows as an infringing product was not an abuse of the trial court’s discretion because MIT itself urged, successfully, that discovery be delayed, and thus MIT’s reliance on uncompleted discovery was not an excuse for amending its infringement contentions.

Whether Subject Matter Was Surrendered Is Determined by an Objective Observer

Jason K. Panda

Judges: Schall (concurring-in-part, dissenting-in-part), Archer, Dyk (author)

[Appealed from N.D. Ill., Judge Hart]

In *Kim v. ConAgra Foods, Inc.*, Nos. 05-1414, -1420 (Fed. Cir. Sept. 20, 2006), the Federal Circuit affirmed the district court’s judgment of noninfringement of U.S. Patent No. Re. 36,355 (“the ’355 patent”) and that the ’355 patent is not invalid.

Yoon Ja Kim is the holder of the '355 patent, which relates to breadmaking. The '355 patent claims a combination of ascorbic acid and food acid that serves as an alternative to potassium bromate, which was widely used to improve the quality of bread but now is believed to be a carcinogen. Kim originally obtained U.S. Patent No. 5,510,129 for a potassium bromate replacer composition, but Kim surrendered the patent to the PTO and filed a reissue application, alleging that an error had arisen during prosecution. After prosecuting the reissue application, Kim obtained the '355 patent in 1999.

“[T]he recapture rule is aimed at ensuring that the public can rely on a patentee’s admission during prosecution of an original patent.” Slip op. at 15.

In 2001, Kim filed suit against ConAgra Foods, Inc. (“ConAgra”) alleging that ConAgra induced infringement of independent claims 5 and 10 of the '355 patent. Both

claims were directed to “a potassium bromate replacer composition *consisting essentially of*” specific amounts of ascorbic acid and food acid and flour. Claim 10 differs from claim 5 in that it contains the additional limitation of yeast. Kim alleged that ConAgra required licensees of its Healthy Choice® brand name to use its recipes, and that the products infringed claims 5 and 10 of the '355 patent. ConAgra stipulated that the recipes for the accused products used ascorbic acid and food acid in the claimed ranges. ConAgra filed a counterclaim for DJ of invalidity and noninfringement of the '355 patent. ConAgra also moved for SJ of invalidity based on the recapture rule. The district court denied ConAgra’s motion, and the case went to trial.

During trial, after each party’s case-in-chief, the opposing party moved for JMOL, and the district court reserved ruling on both motions. The jury found that the asserted claims of the '355 patent were not invalid; that ConAgra had induced infringement of claim 10 with the

licensing of its Healthy Choice® 7-Grain and Whole Grain products, but that the inducement was not willful; and that claim 5 and the dependent claims were not infringed. ConAgra renewed its motion for JMOL, and the district court partially granted the motion, holding that claim 10 was not infringed. The district court entered final judgment, finding the '355 patent not infringed and not invalid.

On appeal, the Federal Circuit first considered the district court’s claim construction and jury charge regarding the phrase “[a] potassium bromate replacer composition” in both claims 5 and 10 of the '355 patent. The Court concluded that while the specification does not explicitly define the term “potassium bromate replacer,” it does make clear that the claimed potassium bromate replacer is an oxidizing agent. Accordingly, the Federal Circuit found no error in the district court’s construction of “potassium bromate replacer” as a composition that performs essentially the same function in the breadmaking process as potassium bromate, which is to strengthen dough, increase loaf volume, and contribute to fine crumb grain.

The Federal Circuit affirmed the district court’s finding that the accused products did not infringe. Because it was undisputed that the accused products included ascorbic acid, food acid, and yeast in the proportions claimed, the key question shifted to whether the claimed ingredients in the accused product satisfied the functionality limitations. The Court noted that Kim did not prove infringement as the testimony she presented was conclusory, unsupported by examinations or tests of the actual accused products, and based upon analogy; whereas, ConAgra presented evidence that different ingredients in its recipe affected functionality. Consequently, the Federal Circuit agreed with the district court’s decision to grant JMOL to ConAgra on claim 10 and the jury’s verdict of noninfringement of claim 5 for the same reasons.

The Federal Circuit also affirmed the district court's denial of ConAgra's motion for JMOL of invalidity based on the recapture doctrine. In reaching its decision, the Court focused on whether the broader aspects of the reissued claims relate to "surrendered" subject matter. The Court explained that "in determining whether 'surrender' of subject matter has occurred, the proper inquiry is whether an objective observer viewing the prosecution history would conclude that the purpose of the patentee's amendment or argument was to overcome prior art and secure the patent." Slip op. at 15. This ensures that the public can rely on a patentee's admission during prosecution of the original patent.

With respect to ConAgra's allegation that Kim surrendered a nonphosphate potassium bromate replacer composition, the Federal Circuit found that the prosecution history refutes ConAgra's argument that phosphate was added by Kim to overcome a rejection. Rather, Kim overcame the obviousness rejection with other amendments, and there was no indication why Kim added the phosphate limitation at the same time. With respect to ConAgra's allegation that Kim surrendered a potassium bromate replacer composition with a food acid range of 0.015-0.2 parts per 100 parts flour, the Court found that Kim's reason for changing the range was not based on obviousness considerations and that the Examiner had not indicated that the original range was obvious in light of the prior art.

Finally, addressing claims of anticipation and obviousness, the Federal Circuit concluded that the jury verdict finding the claims not invalid was supported by substantial evidence. In accepting the verdict, the Court noted that the burden was on ConAgra to establish invalidity by clear and convincing evidence and they had failed to do so. The Court explained that ConAgra made virtually no effort to show that the asserted prior art disclosed the functions of potassium bromate. Moreover, there was substantial evidence that the prior art did not

contain the claimed proportions of ascorbic and food acids. Thus, the prior art was not anticipatory nor did it render the '355 patent obvious.

Judge Schall concurred-in-part and dissented-in-part. While he agreed with the majority's opinion regarding recapture and invalidity issues, he disagreed with the majority's construction of the term "potassium bromate replacer" in the '355 patent. He believed that Kim acted as her own lexicographer in defining the term "potassium bromate replacer" as "a slow acting oxidant that is functional throughout the entire manufacturing process." Accordingly, Judge Schall would have vacated the decision of the district court and remanded for an infringement analysis under this claim construction.

District Court Did Not Abuse Its Discretion in Finding Low Materiality of a Prior Art Reference and No Intent to Deceive

Michael V. O'Shaughnessy

Judges: Newman, Mayer, Bryson (author)

[Appealed from S.D. Iowa, Judge Gritzner]

In *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, Nos. 05-1479, -1480 (Fed. Cir. Sept. 25, 2006), the Federal Circuit affirmed the district court's ruling that U.S. Patent No. 5,382,714 ("the '714 patent") was nonobvious and enforceable, and affirmed the district court's award of costs. The Federal Circuit also affirmed the district court's ruling of noninfringement. Additionally, the Federal Circuit vacated the district court's pretrial order striking a supplemental expert report, and remanded for consideration of that report.

“Even when a court finds that the patentee failed to disclose material information to the PTO and acted with deceptive intent, the court retains discretion to decide whether the patentee’s conduct is sufficiently culpable to render the patent unenforceable.”
Slip op. at 8-9.

Kemin Foods, L.C. (“Kemin”) is the assignee of U.S. Patent No. 5,648,564 (“the ’564 patent”), which relates to a process for producing purified lutein (a carotenoid, or naturally occurring pigment) that is extracted from plants and incorporated into health supplements. Kemin is also the exclusive licensee of the ’714 patent, which is directed to a product consisting essentially of pure lutein crystals “substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract.” Kemin brought suit against Pigmentos Vegetales Del Centro S.A. de C.V. (“PIVEG”) for infringement of both the ’564 and ’714 patents. PIVEG raised several counterclaims. First, PIVEG sought a DJ that the two patents were invalid and unenforceable. In a separate case, PIVEG asserted unfair competition and antitrust counterclaims. A jury returned a verdict finding both patents not invalid. The jury also found the ’714 patent not infringed, but found claim 1 of the ’564 patent infringed under the DOE. The district court found both patents enforceable. As a result, the court declared Kemin the prevailing party, awarded all costs to Kemin, and imposed an injunction against PIVEG.

On appeal, the Federal Circuit first considered PIVEG’s argument that a single reference, a *Poultry Science* article, taught all limitations contained within claim 1 of the ’714 patent, with one exception. PIVEG acquiesced that the *Poultry Science* article did not teach the limitation requiring that the purified lutein product contain no traces of toxic chemicals. PIVEG contended, however, that one of ordinary skill in the art would have understood how to eliminate all traces of toxic chemicals. Despite

its contention, the expert testimony presented by PIVEG established only that one of ordinary skill in the art would have known how to remove some, but not all, toluene from the product. Accordingly, the jury concluded that PIVEG failed to establish by clear and convincing evidence that the ’714 patent, requiring that the product contain no traces of toxic chemicals, was obvious in light of the prior art. The Federal Circuit affirmed the district court’s ruling that substantial evidence existed to support the jury’s verdict.

PIVEG next argued that the ’714 patent was unenforceable because the president of Kemin was aware of the *Poultry Science* article, and was sufficiently involved in prosecution, but failed to disclose the article to the PTO. Acting in an advisory capacity, the jury found that the *Poultry Science* article was material, and also found that the president of Kemin intended to deceive the PTO. The district did not necessarily reject the jury’s findings, but concluded that the levels of materiality and intent were not high enough to warrant a finding of inequitable conduct. Though material, the district court concluded that the *Poultry Science* article was not highly material because it did not render the patent invalid (as noted above), and the method disclosed may not have worked as intended without some modification. The district court acknowledged that a need for modification does not necessarily negate materiality, but properly concluded that the ability to duplicate disclosed information may serve as evidence of the level of materiality.

The Federal Circuit also found no error in the district court’s conclusion that the evidence of intent to deceive was not compelling. Whereas the president of Kemin had previously experimented with methods disclosed in the *Poultry Science* article, nearly two years had passed between that time and prosecution of the ’714 patent. Additionally, the president had only tangentially been involved in prosecution. Finally, the district court deemed plausible Kemin’s explanation that the *Poultry Science*

article did not describe a method for lutein production for human consumption. Given the difficulties in removing toxic chemicals from lutein for human consumption, the district court found the failure to recognize the applicability of the *Poultry Science* article to the claimed invention reasonable. The Federal Circuit, citing the district court's discretion in making such determinations, found no error in the denial of PIVEG's claim of unenforceability.

The Federal Circuit next considered PIVEG's assertion that the '564 patent should be declared unenforceable because Kemin failed to inform the PTO that Kemin, as well as others within the industry, had previously used propylene glycol to produce poultry pigments. The district court accepted Kemin's argument that, while it was undisputed that many within the industry had used propylene glycol to produce pigments, no one was aware that such a process produced lutein crystals. Whereas one of the inventors of the '564 patent noted the presence of crystals during these processes, he remained unaware of the composition of the crystals, and had no reason to expect that the crystals produced were lutein. The Federal Circuit also considered the proffered explanation reasonable and found no error in the district court's rejection of PIVEG's inequitable conduct allegation.

Next, PIVEG argued that Kemin should not have been awarded full costs pursuant to Fed. R. Civ. P. 54(d) because Kemin only prevailed on one of two infringement claims. The Court quickly dismissed this argument, reasoning that the failure of a party to succeed on all claims does not divest that party of their status as a prevailing party. Moreover, Kemin had prevailed on at least one claim of infringement. PIVEG next argued that it had prevailed because its conduct was not affected by the entry of the injunction because it believed its modified process, which did not use propylene glycol, was not subject to the injunction. Additionally, PIVEG noted that the advisory jury verdict on inequitable conduct established that Kemin's

patent was unenforceable. The Federal Circuit rejected PIVEG's argument, noting that PIVEG had, in fact, ultimately lost on each of those issues.

Alternatively, PIVEG argued that the district court should have apportioned costs based upon the "relative success" of the parties. Under the circumstances presented, the Court concluded that the district court had not abused its discretion in refusing to apportion costs. Rather, "[c]ost awards are committed to the discretion of the district courts, and there is no rule requiring courts to apportion costs according to the relative success of the parties." Slip op. at 12.

On cross appeal, Kemin challenged the jury verdict of noninfringement of claims 1, 2, and 4 of the '714 patent. Kemin did not challenge the construction of the asserted claims, but argued only that no reasonable juror could conclude that PIVEG's products fell outside of the claim limitation requiring the lutein composition to be "substantially free from other carotenoids." As the district court had construed this limitation to require "significantly less than 10% of other carotenoids," Kemin cited a range of 6.14-9.86% of other carotenoids in PIVEG samples as evidence of direct infringement, or infringement under the DOE. Deferring to the district court's opinion, the Federal Circuit rejected this challenge, holding "even if the jury accepted Kemin's carotenoid measurements, it could reasonably conclude that although PIVEG's products had less than 10% of other carotenoids, they did not have 'significantly less than 10% of other carotenoids.'" *Id.* at 15.

Alternatively, the Federal Circuit held that a finding of noninfringement could properly have been based upon a limitation requiring that the product contain "no traces of toxic chemicals." Although Kemin argued that the district court should have instructed the jury that this limitation required a level of toxic chemicals below the toxic thresholds established by the FDA, the Court held that the record did not

support such a position. The Court therefore affirmed the finding of noninfringement because PIVEG's products contain traces of toxic chemicals, even though the levels of those toxic chemicals was not high enough to cause illness or death in humans.

Kemin also challenged a decision by the magistrate judge to strike Kemin's supplemental expert report regarding infringement of process claim 5 of the '714 patent. The magistrate judge had excluded the report on grounds that Kemin had not previously alleged infringement of this claim, and essentially amended its complaint by adding an allegation of infringement of claim 5. Contrary to the magistrate judge's findings, however, the Federal Circuit concluded that Kemin had reserved its rights to pursue infringement of additional claims. Additionally, Kemin had diligently pursued discovery to determine whether PIVEG infringed the process claim, but had experienced difficulty in obtaining information about PIVEG's process. The Federal Circuit observed that "as soon as it obtained sufficient information about PIVEG's process, Kemin provided a detailed analysis of its claim 5 infringement contentions," *id.* at 19, and held that under such circumstances, the supplemental expert report should have been allowed. Accordingly, the Federal Circuit concluded that because the supplemental report essentially provided the sole evidentiary basis for Kemin's allegations of infringement of the process claim, Kemin had, in effect, been precluded from pursuing its claim for infringement of claim 5 of the '714 patent. Thus, the Federal Circuit vacated the order excluding the report and remanded for consideration of Kemin's allegations of infringement of claim 5 of the '714 patent.

Also on cross appeal, Kemin sought a modification of the permanent injunction barring PIVEG from practicing a process that infringes claims 1 and 2 of the '564 patent. Kemin argued that PIVEG had evaded the scope of the permanent injunction by employing a modified, nonpropylene-glycol-based process.

Accordingly, Kemin argued that the injunction should be modified to cover all of PIVEG's processes, including processes not using propylene glycol. Kemin contended that PIVEG's modified processes could still infringe claim 5 of the '714 patent, which does not require the use of propylene glycol. The Federal Circuit was unpersuaded by Kemin's argument, given that the injunction was granted upon Kemin's showing of a substantial likelihood that the processes used by PIVEG infringed claim 1 of the '564 patent. As the question of infringement of claim 5 of the '714 patent was to be considered on remand, the Federal Circuit refused to expand the injunction at that time, but left that question open for consideration by the district court on remand.

PTO Has Authority to Exclude Attorney from Practicing Before PTO Based on Disbarment in Other Jurisdictions

Courtney B. Meeker

Judges: Newman, Lourie (author), Rader

[Appealed from D.D.C., Judge Huvelle]

In *Sheinbein v. Dudas*, No. 06-1161 (Fed. Cir. Sept. 25, 2006), the Federal Circuit affirmed the district court's decision to sustain the PTO's exclusion of Sol Scheinbein from practice before the PTO.

Scheinbein was a member of the bars of the District of Columbia and the State of Maryland, and registered to practice before the PTO. In 1997, he helped his son flee to Israel after learning that his son was being investigated for murder. In 2001, the Maryland Court of Appeals held that Scheinbein committed the criminal act of obstructing or hindering a police officer and engaged in conduct prejudicial to the administration of justice. Based on those

findings, Scheinbein was barred from practicing law in Maryland in 2002, and he was subsequently barred from practicing in the District of Columbia in 2004 as reciprocal discipline for his misconduct in Maryland.

In 2004, the PTO's Office of Enrollment and Discipline instituted a disciplinary proceeding pursuant to 37 C.F.R. § 10.134, seeking to exclude Scheinbein from practicing before the PTO based on his disbarments. The ALJ issued an Initial Decision on SJ that Scheinbein should be excluded from practicing before the PTO. Scheinbein appealed to the Director of the PTO, who adopted the ALJ's decision and imposed the sanction of excluding Scheinbein from practice before the PTO. Scheinbein then appealed to the district court, who granted the PTO's motion for SJ of affirmance and dismissed the case.

On appeal, the Federal Circuit affirmed the district court's decision to sustain the PTO's exclusion of Scheinbein from practicing before the PTO. The Court held that the PTO has the statutory authority to exclude Scheinbein based on his prior disbarments and that the statute of limitations does not preclude the exclusion.

With respect to the PTO's statutory authority, the Federal Circuit held that 35 U.S.C. § 32 provides that the PTO has the authority to

exclude from practice before the PTO a practitioner "shown to be incompetent or disreputable, or guilty of gross misconduct, or who does not comply with the regulations established under section 2(b)(2)(D)," which delegates authority to the PTO to establish regulations governing conduct. The Court explained that, based on the plain language of 37 C.F.R. § 10.23(c)(5), one of the disciplinary rules enacted pursuant to the PTO's statutory authority, "a practitioner may be found unfit to practice based solely on his disbarment in another jurisdiction." Slip op. at 6. The Court explained that the exclusion is based on the finding of another jurisdiction regarding the conduct, not the conduct itself. Thus, Scheinbein's prior disbarments violated § 10.23, and the PTO properly excluded him from practice before the PTO.

With respect to the five-year statute of limitations imposed by 28 U.S.C. § 2462, the Federal Circuit held that the PTO's filing of its complaint in 2004 occurred within the limitations period because the basis for the complaint was Scheinbein's violation of § 10.23, which occurred at the time of his disbarments in 2002 and 2004, not at the time of the underlying conduct in 1997. The Court explained that a claim accrues when the factual and legal prerequisites for suit are satisfied, and in this case, those prerequisites were not satisfied until the disbarments occurred.

Abbreviations | Acronyms

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

Looking Ahead

- On November 28, 2006, the Supreme Court will hear oral arguments in *KSR International Co. v. Teleflex, Inc.*, No. 04-1350. This case addresses the Federal Circuit's ruling that a patent may not be found invalid for obviousness unless the prior art sets forth a "teaching, suggestion, or motivation" to combine the prior art teachings in the manner claimed in the patent.
- A number of changes to the Federal Rules of Civil Procedure will become effective December 1, 2006. The changes include amendments relating to electronic discovery and new Fed. R. App. P. 32.1, which requires federal courts to allow attorneys to cite unpublished opinions that issue on or after January 1, 2007. Also included are changes relating to inadvertent disclosures of privileged material.

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Last Month at the Federal Circuit



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